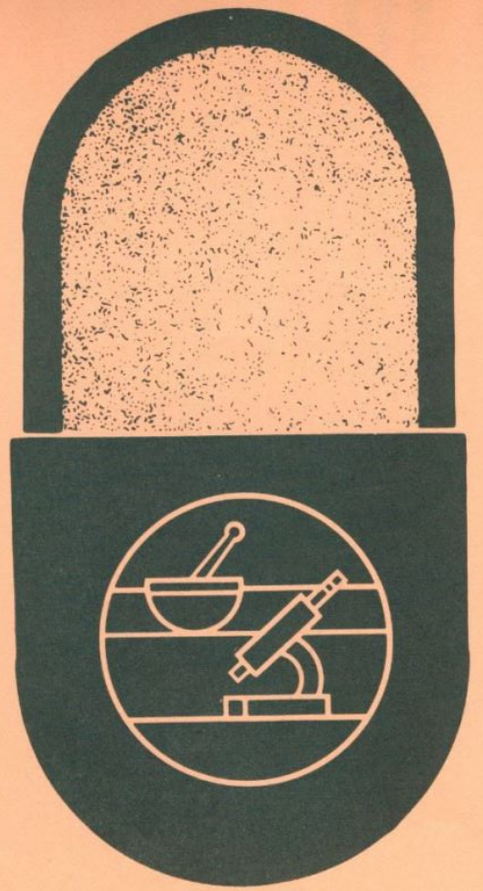
CUMULATIVE
SUPPLEMENT 5
JAN'91-MAY'91



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

11TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

Prepared By
Division of Drug Information Resources
Office of Management
Center for Drug Evaluation and Research, FDA

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

11TH EDITION

Cumulative Supplement

May 1991

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CUMULATIVE SUPPLEMENT 5

MAY 1991

1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 11th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations, over-the-counter (OTC) drug products that require approved applications as a condition of marketing, drug products with approval under Section 505 of the Act administered by the Division of Blood and Blood Products and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

The Cumulative Supplement provides, among other things, information on newly approved drugs and, if necessary, revised therapeutic equivalence evaluations and updated patent and exclusivity data. The Addendum contains appropriate drug patent and exclusivity information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984" for the Prescription, OTC, and Drug Products with Approval under Section 505 of the Act Administered by the Division of Blood and Blood Products lists.

The Patent and Exclusivity Lists are arranged in alphabetical order by active ingredient name. For those products with multiple active ingredients, only the first active ingredient (in alphabetical sort) will appear. In addition, the trade name will be displayed to the right of the active ingredient name for each product, along with the application number and product number (FDA's internal file number). All patents with their expiration dates are displayed for each application number. Use patents are indicated with the symbol "U" followed by a number representing a specific use. Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the exclusivity expires. Refer to the Exclusivity Terms section in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations.

Because all parts of the publication are subject to changes, additions, or deletions, the List must be used in conjunction with the most current Cumulative Supplement. Users may wish to place an asterisk (*) to the left of the ingredient(s) in the List to indicate that changes to that entry appear in the Cumulative Supplement.

Drug product information is provided in each Cumulative Supplement for completeness to assist in locating the proper place in the List for the revision. [Strength(s) which already exist in the List will not be repeated for context.]

The presence of any therapeutic equivalence code indicates that the drug product is multisource; the deletion of a therapeutic equivalence code indicates that the drug product has become single source. (An infrequent exception exists when a therapeutic equivalence code is revised. In that case the deletion of the therapeutic equivalence code is followed immediately by the addition of the revised one.)

Additions new to the Prescription Drug Product List, OTC Drug Product List, and the Patent and Exclusivity Data are indicated by the symbol >ADD> to the left of the line on which new information exists. The >ADD> symbol is then dropped in subsequent Cumulative Supplements for that item. A newly approved product is also identified by a lozenge (⌑) to the right of its strength which remains throughout all Cumulative Supplements for this edition.

Deletions new to the Prescription Drug Product List, OTC Drug Product List, and the Patent and Exclusivity Data are indicated by the symbol >DLT> (DELETE) to the left of the line containing overstruck print. The >DLT> symbol is dropped in subsequent Cumulative Supplements for that item. The overstruck print remains in the Prescription Drug Product List and OTC Drug Product Lists in all Cumulative Supplements for this edition. However, the overstruck print in the Patent and Exclusivity Data is dropped in subsequent Cumulative Supplements.

Products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the " ∋ " symbol to designate their non-marketed status. All products having a " ∋ " symbol in the 12th Cumulative Supplement of the 11th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 12th Edition.

1.2 PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL

Drug products in this category (1) initially received approval only on the basis of safety before effectiveness studies were required, or (2) were conditionally approved under the temporary exemption that allowed these products to be marketed while effectiveness studies were being conducted. Listed below are those drugs which are now required to revise their labeling and provide additional information necessary for full approval on the basis of requirements listed in the Federal Register. As approval is granted by the Agency for a specific product, based on additional information submitted by the applicant, the product will be included in the appropriate Drug Product List.

Products	Federal Register Reference
Nitroglycerin (capsule, controlled release;oral)	SEP 7, 1984 (49 FR 35428)
Nitroglycerin (tablet, controlled release;oral)	SEP 7, 1984 (49 FR 35428)
Nitroglycerin (tablet, controlled release;buccal)	JUL 5, 1985 (50 FR 27688)
Tranylcypromine Sulfate	MAR 22, 1984 (49 FR 10708)

1.3 CHANGE OF A THERAPEUTIC EQUIVALENCY CODE FOR A DRUG ENTITY

Methylphenidate Hydrochloride:

In its initial considerations, the Agency did not classify methylphenidate hydrochloride (MPD) as having an actual or potential bioequivalence problem (42 FR 1624, January 7, 1977). MPD in oral tablet form (Ritalin™, manufactured by Ciba Pharmaceuticals) is a DESI drug product that was raised to the effective status on October 7, 1970 (35 FR 15771). MPD in tablet form remained single source until December 23, 1977 when it became available from MD Pharmaceutical. In the first and subsequent editions of the "Orange Book" this drug product has been coded **AA**.

Recently, FDA's Therapeutic Inequivalence Action Coordination Committee (TIACC) investigated a report from the Kaiser Permanente Medical Care Program in Oakland, California, suggesting therapeutic inequivalence regarding duration of action in a marketed lot of MD Pharmaceutical MPD tablets. Samples from MD Pharmaceutical and Ciba were tested in accordance with USP dissolution test procedures by an FDA field laboratory. Although both products met the single point USP criteria of not less than 75% of the labeled amount of MPD dissolved within 45 minutes, the dissolution profile of the MD Pharmaceutical product was much faster than that of the Ciba product.

Based on these in vitro dissolution data, FDA commissioned an in vivo bioequivalence study under its extramural contract research program. The bioequivalence study indicated that at one-half and three-fourths hours after administration of a single 20 mg dose, somewhat more of MD Pharmaceutical's product had been absorbed compared to Ciba's Ritalin. However, the MD Pharmaceutical MPD 20 mg tablets met FDA's criteria for rate and extent of absorbtion, and were considered to be bioequivalent to Ciba's Ritalin 20 mg tablets.

Because of the in vitro dissolution data coupled with new information discovered during the course of this evaluation, the FDA has proposed a change in the therapeutic equivalence code from **AA** to **BP** for listed MPD tablets. This change requires that firms submitting an ANDA for MPD tablets submit an acceptable in vivo bioequivalence study to gain approval in addition to submission of all previously required information.

Agency reasons for considering this change in the equivalence code is as follows:

1) Although early work suggested that MPD tablets are completely absorbed, recent studies utilizing more specific techniques calculated the relative bioavailability to be 11 to 53%. (Chan et al: Pediatrics, **72**, 56-59, 1983). This raised concerns regarding possible approval of a superbioavailable drug product.

2) The current dl-MPD pharmacological activity derives primarily from the d isomer which may exhibit non-linear kinetics. (Srinivas et al: Journal of Pharmacology and Experimental Therapeutics, **241**, 300-306, 1987).

3) The previously cited in vitro dissolution data suggesting that substantial differences in in vitro dissolution may exist between different formulations of MPD.

The Agency invites written comments and scientific data regarding the Agency's proposal to change the therapeutic equivalence code for listed MPD oral tablets from **AA** to **BP**. The comment period will be 60 days from the first day in the monthly Supplement.

1.4 THE B* THERAPEUTIC EQUIVALENCE CODE

Drug products requiring further FDA investigation and review to determine therapeutic equivalence.

The code **B*** is assigned to products that were previously assigned an **A** code if FDA receives new information that raises a significant question regarding therapeutic equivalence that can be resolved only through further Agency investigation and/or review of data and information submitted by the applicant. The **B*** code signifies that the Agency will take no position regarding the therapeutic equivalence of the product until the Agency completes its investigation and review.

1.5 APPLICANT (NAME) CHANGES

Because it is not practical to identify in the Cumulative Supplement each and every product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name, the cumulation of these transfers and name changes will be identified in this section only. Where only partial approved product lines are transferred between applicants, each approved product involved will appear as an applicant name change in the Cumulative Supplement.

APPLICANT (NAME) CHANGES

FORMER APPLICANT (NAME)	NEW APPLICANT (NAME)	ABBREVIATED NAME
CORD LABORATORIES INC	GENEVA PHARMACEUTICALS INC	GENEVA
PHARMACIA LABORATORIES DIV PHARMACIA INC	KABI PHARMACIA	KABI

1.6 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

This report provides summary counts derived from the product information in the Prescription Drug Product List and the current Cumulative Supplement. Products included in the counts are domestically marketed drug products approved for both safety and effectiveness under sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act. Excluded are approved drug products marketed by distributors; those marketed solely abroad; and those now regarded as medical devices, biologics or foods.

The baseline column (Dec 1990) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

DEFINITIONS

Drug Product

For this report, a drug product is the representation in the Prescription Drug Product List of an active moiety (molecular entity and its salts, esters and derivatives) either as a single ingredient or as a combination product provided in a specific dosage form and strength for a given route of administration with approval for marketing by a firm under a particular generic or trade name.

New Molecular Entity

A new molecular entity is considered an active moiety that has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or as part of a combination.

A new molecular entity is considered an active moiety that has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or as part of a combination.

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

COUNTS CUMULATIVE BY QUARTER

CATEGORIES COUNTED	DEC 1990	MAR 1991	JUN 1991	SEP 1991
DRUG PRODUCTS LISTED	10123	9953		
SINGLE SOURCE	2030 (20.1%)	2090 (21.0%)		
MULTISOURCE	8093 (79.9%)	7863 (79.0%)		
THERAPEUTICALLY EQUIVALENT	7222 (71.3%)	7061 (71.0%)		
NOT THERAPEUTICALLY EQUIVALENT	752 (7.4%)	660 (6.6%)		
EXCEPTIONS[1]	119 (1.2%)	142 (1.4%)		
NEW MOLECULAR ENTITIES APPROVED	--	5		
NUMBER OF APPLICANTS	400	408		

[1]Amino acid-containing products of varying composition (see Introduction, page 1-8 of the List).

ACETAMINOPHEN; CODEINE PHOSPHATE

CAPSULE; ORAL

>DLT>		PROVAL #3		
>DLT>/AA/		REID/ROWELL	325MG;30MG	N85685/001
>ADD>	@	REID ROWELL	325MG;30MG	N85685 001

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE NO. 2

/AA/		AM/THERAP	300MG;15MG	N89481/001/MAR/03,/1987
	@	AM THERAP	300MG;15MG	N89481 001 MAR 03, 1987

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL

PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

/AB/		CHELSEA	325MG;50MG	N71336/001/DEC/11,/1986/
/AB/			650MG;100MG	N71337/001/DEC/11,/1986/
	B*	CHELSEA	325MG;50MG	N71336 001 DEC 11, 1986
	B*		650MG;100MG	N71337 001 DEC 11, 1986

ACETIC ACID, GLACIAL

SOLUTION/DROPS; OTIC

>DLT>		DR'EX		
>DLT>/AT/		NORWICH/EATON	2%	N86845/001
>ADD>	@	NORWICH EATON	2%	N86845 001

ACETIC ACID, GLACIAL; HYDROCORTISONE

SOLUTION/DROPS; OTIC

>DLT>		DR'EX HC		
>DLT>/AT/		NORWICH/EATON	2%;1%	N86844/001
>ADD>	@	NORWICH EATON	2%;1%	N86844 001

ACYCLOVIR

TABLET; ORAL

ZOVIRAX

BURROUGHS WELLCOME	400MG*		N20089 001 APR 30, 1991
	800MG*		N20089 002 APR 30, 1991

ALBUTEROL SULFATE

TABLET; ORAL

ALBUTEROL SULFATE

AB	DANBURY	EQ 2MG BASE*		N72629 001 JAN 31, 1991
AB		EQ 4MG BASE*		N72630 001 JAN 31, 1991
AB	MYLAN	EQ 2MG BASE*		N72893 001 JAN 17, 1991
AB		EQ 4MG BASE*		N72894 001 JAN 17, 1991

ALGLUCERASE

INJECTABLE; INJECTION

CEREDASE

GENZYME	80 UNITS/ML*		N20057 003 APR 05, 1991

ALLOPURINOL

TABLET; ORAL

ALLOPURINOL

/AB/		PUREPAC	100MG	N70579/001/APR/14,/1986/
/AB/			300MG	N70580/001/APR/14,/1986/
	@	PUREPAC	100MG	N70579 001 APR 14, 1986
	@		300MG	N70580 001 APR 14, 1986

ALPRAZOLAM

TABLET; ORAL

XANAX

/3/		UPJOHN	2MG	N18276/004/NOV/27,/1985/
		UPJOHN	2MG	N18276 004 NOV 27, 1985

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL

PERPHENAZINE AND AMITRIPTYLINE HCL

/AB/	/CHELSEA/	/10MG;2MG/	/N71384/001/ /NOV/03,/1986/
/AB/		/10MG;4MG/	/N71386/001/ /NOV/03,/1986/
/AB/		/25MG;2MG/	/N71385/001/ /NOV/03,/1986/
/AB/		/25MG;4MG/	/N71387/001/ /NOV/03,/1986/
B*	CHELSEA	10MG;2MG	N71384 001 NOV 03, 1986
B*		10MG;4MG	N71386 001 NOV 03, 1986
B*		25MG;2MG	N71385 001 NOV 03, 1986
B*		25MG;4MG	N71387 001 NOV 03, 1986
B*		50MG;4MG	N71558 001 MAR 02, 1987
/BX/		/50MG;4MG/	/N71558/001/ /MAR/02,/1987/

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE; VITAMIN A; VITAMIN E

INJECTABLE; INJECTION

M,V,I,-12 LYOPHILIZED

/AP/	/ARMOUR/	/100MG/VIAL;0.06MG/VIAL; 0.005MG/VIAL;15MG/VIAL;5UGM/VIAL; 0.4MG/VIAL;40MG/VIAL;4MG/VIAL; 3.6MG/VIAL;3MG/VIAL;1MG/VIAL; 10MG/VIAL/	/N18933/002/ /AUG/08,/1985/
AP	ASTRA	100MG/VIAL;0.06MG/VIAL; 0.005MG/VIAL;15MG/VIAL;5UGM/VIAL; 0.4MG/VIAL;40MG/VIAL;4MG/VIAL; 3.6MG/VIAL;3MG/VIAL;1MG/VIAL; 10MG/VIAL	N18933 002 AUG 08, 1985

ASPIRIN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL

/BUTALBITAL W/ ASPIRIN AND CAFFEINE/

/AB/	/CHELSEA/	/325MG;50MG;40MG/	/N86231/002/ /FEB/12,/1985/

> DLT >
> DLT >
> ADD >
> ADD >

ASPIRIN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL

BUTALBITAL, ASPIRIN AND CAFFEINE

AB	CHELSEA	325MG;50MG;40MG	N86231 002 FEB 12, 1985

TABLET; ORAL

/BUTALBITAL W/ ASPIRIN AND CAFFEINE/

/AB/	/CHELSEA/	/325MG;50MG;40MG/	/N86237/002/ /MAR/23,/1984/

BUTALBITAL, ASPIRIN AND CAFFEINE

AB	CHELSEA	325MG;50MG;40MG	N86237 002 MAR 23, 1984

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

ORPHENGESIC

B*	PAR	385MG;30MG;25MG	N71642 001 JUN 23, 1987
/BX/		/385MG;30MG;25MG/	/N71642/001/ /JUN/23,/1987/

ORPHENGESIC FORTE

B*	PAR	770MG;60MG;50MG	N71643 001 JUN 23, 1987
/BX/		/770MG;60MG;50MG/	/N71643/001/ /JUN/23,/1987/

BACLOFEN

TABLET; ORAL

BACLOFEN

/AB/	/PHARM/BASICS/	/10MG/	/N71260/001/ /MAY/06,/1988/
/AB/		/20MG/	/N71261/001/ /MAY/06,/1988/
B*	PHARM BASICS	10MG	N71260 001 MAY 06, 1988
B*		20MG	N71261 001 MAY 06, 1988

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION

BRETYLIUM TOSYLATE IN DEXTROSE 5% IN PLASTIC CONTAINER

	/ABBOTT/	/800MG/100ML/	/N19008/001/ /APR/16,/1986/
@	ABBOTT	800MG/100ML	N19008 001 APR 16, 1986

BROMPHENIRAMINE MALEATE

TABLET; ORAL

		BROMPHENIRAMINE MALEATE		
> DLT > / AA /	/ PAR /	/ 4MG /	/ N87009 / 001 /	
> ADD >	@ PAR	4MG	N87009 001	

BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

> DLT >	/ ELIXIR; / ORAL /			
> DLT >	/ BIPHETAP /			
> DLT >	/ PHARM / BASICS /	/ 4MG / 5ML; 25MG / 5ML /	/ N88687 / 001 /	
> DLT >			/ SEP / 26, / 1984 /	
> ADD >	@ PHARM BASICS	4MG/5ML;25MG/5ML	N88687 001	
> ADD >			SEP 26, 1984	

BUTABARBITAL SODIUM

TABLET; ORAL

		BUTABARBITAL SODIUM		
/ AA /	/ CORD /	/ 15MG /	/ N84292 / 003 /	
			/ FEB / 09, / 1982 /	
/ AA /		/ 30MG /	/ N84272 / 002 /	
	@ CORD	15MG	N84292 003	
			FEB 09, 1982	
	@	30MG	N84272 002	
/ AA /	/ WHITE / TOWNE / PAULSEN /	/ 15MG /	/ N83325 / 002 /	
	@ WHITE TOWNE PAULSEN	15MG	N83325 002	

CALCITONIN, SALMON

INJECTABLE; INJECTION

	CALCIMAR		
AP	RHONE POULENC RORER	200 IU/ML	N17769 001
	MIACALCIN		
AP	SANDOZ	200 IU/ML*	N17808 002
			MAR 29, 1991

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE

/ INJECTABLE; / INJECTION /			
/ ACETATED / RINGER'S / IN / PLASTIC / CONTAINER /			
/ MCGAW /	/ 20MG / 100ML; 30MG / 100ML; 380MG / 100ML; / 600MG / 100ML /	/ N18725 / 001 /	
		/ NOV / 29, / 1982 /	
@ MCGAW	20MG/100ML;30MG/100ML;380MG/100ML; 600MG/100ML	N18725 001	
		NOV 29, 1982	

CALCIUM GLUCEPTATE

INJECTABLE; INJECTION

		CALCIUM GLUCEPTATE		
/ AP /	/ ABBOTT /	/ EQ 90MG CALCIUM / 5ML /	/ N83159 / 001 /	
	@ ABBOTT	EQ 90MG CALCIUM/5ML	N83159 001	

CARBAMAZEPINE

TABLET; ORAL

		CARBAMAZEPINE		
/ AB /	/ PHARM / BASICS /	/ 200MG /	/ N70300 / 001 /	
			/ MAY / 15, / 1986 /	
B*	PHARM BASICS	200MG	N70300 001	
			MAY 15, 1986	

CARBIDOPA; LEVODOPA

> ADD >	TABLET, EXTENDED RELEASE; ORAL			
> ADD >	SINEMET CR			
> ADD >	MSD	50MG;200MG*	N19856 001	
> ADD >			MAY 30, 1991	

CEFADROXIL

CAPSULE; ORAL

		ULTRACEF		
> DLT > / AB /	/ BRISTOL /	/ EQ 500MG BASE /	/ N62378 / 001 /	
> DLT >			/ MAR / 16, / 1982 /	
> ADD >	@ BRISTOL	EQ 500MG BASE	N62378 001	
> ADD >			MAR 16, 1982	

POWDER FOR RECONSTITUTION; ORAL

		ULTRACEF		
> DLT > / AB /	/ BRISTOL /	/ EQ 125MG BASE / 5ML /	/ N62376 / 001 /	
> DLT >			/ MAR / 16, / 1982 /	
> DLT > / AB /		/ EQ 250MG BASE / 5ML /	/ N62376 / 002 /	
> DLT >			/ MAR / 16, / 1982 /	
> DLT > / AB /		/ EQ 500MG BASE / 5ML /	/ N62376 / 003 /	
> DLT >			/ MAR / 16, / 1982 /	
> ADD >	@ BRISTOL	EQ 125MG BASE/5ML	N62376 001	
> ADD >			MAR 16, 1982	
> ADD >	@	EQ 250MG BASE/5ML	N62376 002	
> ADD >			MAR 16, 1982	
> ADD >	@	EQ 500MG BASE/5ML	N62376 003	
> ADD >			MAR 16, 1982	

CEFADROXIL

TABLET; ORAL
ULTRACEF

> DLT >	/AB/	/BRISTOL/	/EQ 1GM BASE/	/N62408/001/ /AUG/31,/1982/
> DLT >				
> ADD >		@ BRISTOL	EQ 1GM BASE	N62408 001 AUG 31, 1982
> ADD >				

CEFAZOLIN SODIUM

INJECTABLE; INJECTION
ANCEF IN PLASTIC CONTAINER

	BAXTER	EQ 10MG BASE/ML¤	N63002 001 MAR 28, 1991
		EQ 20MG BASE/ML¤	N63002 002 MAR 28, 1991

CEPHALEXIN

POWDER FOR RECONSTITUTION; ORAL
CEPHALEXIN

AB	SQUIBB MARK	EQ 125MG BASE/5ML¤	N62986 001 APR 18, 1991

CEPHRADINE

CAPSULE; ORAL

		/VELOSEF '250'/		
/AB/		/ERSANA/	/250MG/	/N50548/001/
	@ ERSANA		250MG	N50548 001
		/VELOSEF '500'/		
/AB/		/ERSANA/	/500MG/	/N50548/002/
	@ ERSANA		500MG	N50548 002

CHLORPHENIRAMINE MALEATE

INJECTABLE; INJECTION
CHLORPHENIRAMINE MALEATE

/AP/		/LEMMON/	/10MG/ML/	/N83593/001/
AP		STERIS	10MG/ML	N83593 001

TABLET; ORAL
CHLORPHENIRAMINE MALEATE

		/VITARINE/		
/AA/		/PHENETRON/	/4MG/	/N85837/001/
	@ VITARINE		4MG	N85837 001
/AA/		/LANNETT/	/4MG/	/N80846/001/
	@ LANNETT		4MG	N80846 001

CHLORPROMAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
CHLORPROMAZINE HCL

/AP/		/LEMMON/	/25MG/ML/	/N85591/001/
AP		STERIS	25MG/ML	N85591 001

CHLORTHALIDONE

TABLET; ORAL
CHLORTHALIDONE

/AB/		/SUPERPHARM/	/25MG/	/N87473/001/ /FEB/09,/1983/
	@ SUPERPHARM		25MG	N87473 001 FEB 09, 1983

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION
CLINDAMYCIN PHOSPHATE

/AP/		/LEMMON/	/EQ 150MG BASE/ML/	/N62900/001/ /JUN/08,/1988/
/AP/			/EQ 150MG BASE/ML/	/N63079/001/ /MAR/05,/1990/
AP		STERIS	EQ 150MG BASE/ML	N62900 001 JUN 08, 1988
AP			EQ 150MG BASE/ML	N63079 001 MAR 05, 1990

CLONIDINE HYDROCHLORIDE

TABLET; ORAL
CLONIDINE HCL

/AB/		/DURAMED/	/0.2MG/	/N71102/001/ /AUG/14,/1986/
	@ DURAMED		0.2MG	N71102 001 AUG 14, 1986

CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL
CLORAZEPATE DIPOTASSIUM

/AB/		/PUREPAC/	/3.75MG/	/N71924/001/ /APR/25,/1988/
	@ PUREPAC		3.75MG	N71924 001 APR 25, 1988

CLORAZEPATE DIPOTASSIUM

CYANOCOBALAMIN

CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL
CLORAZEPATE DIPOTASSIUM

/AB/	/SEARLE/	/3.75MG/	/N71727/001/	/DEC/18,/1987/
/AB/		/7.5MG/	/N71728/001/	/DEC/18,/1987/
/AB/		/15MG/	/N71729/001/	/DEC/18,/1987/
	ə SEARLE	3.75MG	N71727 001	DEC 18, 1987
	ə	7.5MG	N71728 001	DEC 18, 1987
	ə	15MG	N71729 001	DEC 18, 1987

TABLET; ORAL
CLORAZEPATE DIPOTASSIUM

> DLT >	/AB/	/AM/THERAP/	/3.75MG/	/N71747/001/	/JUN/09,/1987/
> DLT >	/AB/		/7.5MG/	/N71748/001/	/JUN/09,/1987/
> DLT >	/AB/		/15MG/	/N71749/001/	/JUN/09,/1987/
> ADD >		ə AM THERAP	3.75MG	N71747 001	JUN 09, 1987
> ADD >		ə	7.5MG	N71748 001	JUN 09, 1987
> ADD >		ə	15MG	N71749 001	JUN 09, 1987

CORTISONE ACETATE

INJECTABLE; INJECTION
CORTISONE ACETATE

/BP/	/LEMMON/	/25MG/ML/	/N85677/001/	
/BP/		/50MG/ML/	/N85677/002/	
BP	STERIS	25MG/ML	N85677 001	
BP		50MG/ML	N85677 002	

CYANOCOBALAMIN

INJECTABLE; INJECTION
COBAVITE

/AP/	/LEMMON/	/0.1MG/ML/	/N83013/001/	
/AP/		/1MG/ML/	/N83064/001/	
AP	STERIS	0.1MG/ML	N83013 001	
AP		1MG/ML	N83064 001	

CYANOCOBALAMIN

INJECTABLE; INJECTION
CYANOCOBALAMIN

/AP/	/LEMMON/	/0.1MG/ML/	/N83120/001/	
/AP/		/1MG/ML/	/N83120/002/	
/AP/	/LYPHOMED/	/0.03MG/ML/	/N80510/003/	
/AP/		/0.1MG/ML/	/N80510/001/	
/AP/		/1MG/ML/	/N80510/002/	
	ə LYPHOMED	0.03MG/ML	N80510 003	
	ə	0.1MG/ML	N80510 001	
	ə	1MG/ML	N80510 002	
AP	STERIS	0.1MG/ML	N83120 001	
AP		1MG/ML	N83120 002	

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL
CYCLOBENZAPRINE HCL

> ADD >	AB	MYLAN	10MG¤	N73144 001	
> ADD >				MAY 31, 1991	

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
CYCLOPENTOLATE HCL

AT	STERIS	1%¤	N89162 001	
			JAN 24, 1991	

DANAZOL

CAPSULE; ORAL
DANAZOL

/AB/	/AM/THERAP/	/200MG/	/N71569/001/	/DEC/30,/1987/
B*	AM THERAP	200MG	N71569 001	DEC 30, 1987

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL

DESIPRAMINE HCL

/AB/	/PHARM/BASICS/	/25MG/	/N71864/001/	/SEP/09,/1987/
/AB/		/50MG/	/N71865/001/	/SEP/09,/1987/
/AB/		/75MG/	/N71866/001/	/SEP/09,/1987/
/AB/		/100MG/	/N71867/001/	/SEP/09,/1987/
B*	PHARM BASICS	25MG	N71864 001	SEP 09, 1987
B*		50MG	N71865 001	SEP 09, 1987
B*		75MG	N71866 001	SEP 09, 1987
B*		100MG	N71867 001	SEP 09, 1987

DESMOPRESSIN ACETATE

SOLUTION; NASAL

CONCENTRAID

BX	FERRING	0.01%	N19776 001	DEC 26, 1990
		/0.01%/	/N19776/001/	/DEC/26,/1990/

DDAVP

BX	RHONE POULENC RORER	0.01%	N17922 001	
		/0.01%/	/N17922/001/	

DEXAMETHASONE

TABLET; ORAL

DEXAMETHASONE

/BP/	/CORD/	/0.75MG/	/N80399/001/	
	@ CORD	0.75MG	N80399 001	

DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

/DEXACEN-4/

/AP/	/CENTRAL/PHARMS/	/EQ 4MG PHOSPHATE/ML/	/N84342/001/	
	@ CENTRAL PHARMS	EQ 4MG PHOSPHATE/ML	N84342 001	

DEXAMETHASONE SODIUM PHOSPHATE

/AP/	/LEMMON/	/EQ 4MG PHOSPHATE/ML/	/N84355/001/	
AP	STERIS	EQ 4MG PHOSPHATE/ML	N84355 001	

DEXTROSE

INJECTABLE; INJECTION

DEXTROSE 10% IN PLASTIC CONTAINER

/AP/	/CUTTER/	/10GM/100ML/	/N18564/001/	
	@ CUTTER	10GM/100ML	N18504 001	

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 0.22% IN PLASTIC CONTAINER

/AP/	/MCGAW/	/5GM/100ML;220MG/100ML;/ /450MG/100ML/	/N18268/002/	
	MCGAW	5GM/100ML;220MG/100ML; 450MG/100ML	N18268 002	

DEXTROSE; SODIUM CHLORIDE

INJECTABLE; INJECTION

DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER

/AP/	/CUTTER/	/5GM/100ML;200MG/100ML/	/N18399/001/	
	@ CUTTER	5GM/100ML;200MG/100ML	N18399 001	

DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER

/AP/	/ABBOTT/	/5GM/100ML;300MG/100ML/	/N17799/001/	
	ABBOTT	5GM/100ML;300MG/100ML	N17799 001	
/AP/	/CUTTER/	/5GM/100ML;300MG/100ML/	/N18501/001/	
	@ CUTTER	5GM/100ML;300MG/100ML	N18501 001	

DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

/AP/	/CUTTER/	/5GM/100ML;450MG/100ML/	/N18400/001/	
	@ CUTTER	5GM/100ML;450MG/100ML	N18400 001	

DIATRIZOATE SODIUM

INJECTABLE; INJECTION

/MD-50/

/AP/	/MALLINCKRODT/	/50%/	/N87075/001/	
	@ MALLINCKRODT	50%	N87075 001	

DIAZEPAM

INJECTABLE; INJECTION

DIAZEPAM

/AP/	/LEMMON/	/5MG/ML/	/N70911/001/	/AUG/28,/1986/
/AP/		/5MG/ML/	/N70912/001/	/AUG/28,/1986/
/AP/		/5MG/ML/	/N70930/001/	/DEC/01,/1986/

DIAZEPAM

INJECTABLE; INJECTION
DIAZEPAM

AP	STERIS	5MG/ML	N70911 001 AUG 28, 1986
AP		5MG/ML	N70912 001 AUG 28, 1986
AP		5MG/ML	N70930 001 DEC 01, 1986

TABLET; ORAL
DIAZEPAM

/A/	/SUPERPHARM/	/2MG/	/N70642/001/ /DEC/11,/1985/
/A/		/5MG/	/N70643/001/ /DEC/11,/1985/
/A/		/10MG/	/N70644/001/ /DEC/11,/1985/

DICLOFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC
VOLTAREN

	CIBA	0.1%¤	N20037 001 MAR 28, 1991

DIMENHYDRINATE

INJECTABLE; INJECTION
DIMENHYDRINATE

/AP/	/LEMMON/	/50MG/ML/	/N83531/001/
AP	STERIS	50MG/ML	N83531 001

/TABLET;/ORAL/
/DIMENHYDRINATE/

/AA/	/CHELSEA/	/50MG/	/N85166/001/
	ə CHELSEA	50MG	N85166 001

DIPHENHYDRAMINE HYDROCHLORIDE

ELIXIR; ORAL
DIPHENHYDRAMINE HCL

/AA/	/KV/	/12.5MG/5ML/	/N85621/001/
	ə KV	12.5MG/5ML	N85621 001

INJECTABLE; INJECTION
DIPHENHYDRAMINE HCL

/AP/	/ELKINS/SINN/	/50MG/ML/	/N83183/001/
	ə ELKINS SINN	50MG/ML	N83183 001

DIPHENHYDRAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
DIPHENHYDRAMINE HCL

/AP/	/LEMMON/	/10MG/ML/	/N83533/001/
AP	STERIS	10MG/ML	N83533 001

DIPYRIDAMOLE

TABLET; ORAL
DIPYRIDAMOLE

AB	LEDERLE	25MG¤	N88999 001 FEB 05, 1991
AB		50MG¤	N89000 001 FEB 05, 1991
AB		75MG¤	N89001 001 FEB 05, 1991

DISOPYRAMIDE PHOSPHATE

CAPSULE; ORAL
DISOPYRAMIDE PHOSPHATE

B*	CHELSEA	EQ 100MG BASE	N71020 001 DEC 01, 1986
B*		EQ 150MG BASE	N71021 001 DEC 01, 1986
/BX/		/EQ/100MG/BASE/	/N71020/001/ /DEC/01,/1986/
/BX/		/EQ/150MG/BASE/	/N71021/001/ /DEC/01,/1986/
/AB/	/MYLAN/	/EQ/100MG/BASE/	/N70138/001/ /JUN/14,/1985/
/AB/		/EQ/150MG/BASE/	/N70139/001/ /JUN/14,/1985/
	ə MYLAN	EQ 100MG BASE	N70138 001 JUN 14, 1985
	ə	EQ 150MG BASE	N70139 001 JUN 14, 1985

DOBUTAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
DOBUTREX

	LILLY	EQ 12.5MG BASE/ML	N17820 002
		/EQ/250MG/BASE/VIAL/	/N17820/002/

DOXACURIUM CHLORIDE

INJECTABLE; INJECTION

NUROMAX

BURROUGHS WELLCOME — EQ 1MG BASE/ML* — N19946 001 MAR 07, 1991

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL

DOXEPIN HCL

AB	PUREPAC	EQ 75MG BASE	N72386 001 SEP 08, 1988
AB		EQ 150MG BASE	N72387 001 SEP 08, 1988
AB	ROYCE	EQ 10MG BASE*	N72985 001 MAR 29, 1991
AB		EQ 25MG BASE*	N72986 001 MAR 29, 1991
AB		EQ 50MG BASE*	N72987 001 MAR 29, 1991

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

ADRIAMYCIN PFS

AP	ADRIA	2MG/ML	N50629 001 DEC 23, 1987
AP		200MG/100ML	N50629 002 MAY 03, 1988
AP		2MG/ML*	N63165 001 JAN 30, 1991
AP		200MG/100ML*	N63165 002 JAN 30, 1991

/2MG/ML/ — /N50629/002/ /MAY/03,/1988/

DOXORUBICIN HCL

AP	CETUS BEN VENUE	2MG/ML	N62975 001 MAR 17, 1989

DOXYCYCLINE HYCLATE

TABLET; ORAL

DOXYCYCLINE HYCLATE

/AB/	/CHELSEA/	/EQ 100MG BASE/	/N62392/002/ /MAR/31,/1983/	
	a CHELSEA	EQ 100MG BASE	N62392 002 MAR 31, 1983	

DOXYLAMINE SUCCINATE

TABLET; ORAL

DOXYLAMINE SUCCINATE

> DLT > /AA/	COPLEY	/25MG/	/N88966/001/ /OCT/08,/1985/	

DROPERIDOL

INJECTABLE; INJECTION

DROPERIDOL

/AP/	/ASTRA/	/2.5MG/ML/	/N72020/001/ /OCT/19,/1988/	
	a ASTRA	2.5MG/ML	N72020 001 OCT 19, 1988	

EDETATE DISODIUM

INJECTABLE; INJECTION

DISODIUM EDETATE

/AP/ AP	/LEMMON/ STERIS	/150MG/ML/ 150MG/ML	/N84356/001/ N84356 001	

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HCL W/ EPINEPHRINE

/a/	/LEMMON/	/0.01MG/ML;1%/	/N85463/001/ N85463 001	
	a STERIS	0.01MG/ML;1%		

ERGOLOID MESYLATES

TABLET; SUBLINGUAL

/DEAPRIL-ST/

/AA/	/BRISTOL/MYERS/SQUIBB/1MG/		/N85020/002/ N85020 002	
	a BRISTOL MYERS SQUIBB 1MG			

ERGOLOID MESYLATES

TABLET; SUBLINGUAL
ERGOLOID MESYLATES

/AA/	/KV/	/0.5MG/	/N86265/001/	
/AA/		/1MG/	/N86264/001/	
ə KV		0.5MG	N86265 001	
ə		1MG	N86264 001	

ERYTHROMYCIN

SOLUTION; TOPICAL
ERYTHROMYCIN

AT	CLAY PARK	2%¤	N63038 001	JAN 11, 1991

ESTROGENS, CONJUGATED

TABLET; ORAL
CONJUGATED ESTROGENS

/BP/	/CHELSEA/	/1.25MG/	/N85801/001/	
/BP/		/2.5MG/	/N85826/001/	
/ə/		/0.625MG/	/N85800/001/	
/ə/	/CORD/	/0.3MG/	/N86070/001/	
/ə/		/0.625MG/	/N83761/001/	
/ə/		/1.25MG/	/N83763/001/	
/ə/		/2.5MG/	/N83762/001/	
/ə/	/DURAMED/	/0.3MG¤/	/N86492/001/	
/ə/		/0.625MG¤/	/N83272/001/	
/ə/		/1.25MG¤/	/N83294/001/	
/ə/		/2.5MG¤/	/N83295/001/	
/ə/	/HEATHER/	/0.625MG/	/N83356/001/	
/ə/		/1.25MG/	/N83360/001/	
/ə/		/2.5MG/	/N84650/001/	
/ə/	/PRIVATE/FORM/	/0.625MG/	/N83354/003/	
/ə/		/1.25MG/	/N83592/001/	
/ə/		/2.5MG/	/N85908/001/	
/BP/	/ZENITH/	/0.3MG/	/N88569/001/ NOV/29,/1984/	
/BP/		/0.625MG/	/N83373/001/	
/BP/		/1.25MG/	/N83601/001/	
/BP/		/2.5MG/	/N83602/001/	
ə ZENITH		0.3MG	N88569 001 NOV 29, 1984	
ə		0.625MG	N83373 001	
ə		1.25MG	N83601 001	
ə		2.5MG	N83602 001	

ESTROPIPATE

TABLET; ORAL
OGEN

AB	ABBOTT	0.75MG	N83220 001

ORTHO-EST

AB	JOHNSON RW	0.75MG¤	N89567 001 FEB 27, 1991

ETODOLAC

CAPSULE; ORAL
LODINE

	WYETH AYERST	200MG¤	N18922 002 JAN 31, 1991
		300MG¤	N18922 003 JAN 31, 1991

FENOPROFEN CALCIUM

CAPSULE; ORAL
FENOPROFEN CALCIUM

AB	WARNER CHILCOTT	EQ 200MG BASE¤	N72946 001 APR 30, 1991
AB		EQ 300MG BASE¤	N72472 001 APR 30, 1991

TABLET; ORAL
FENOPROFEN CALCIUM

>DLT>	/AB/	/PHARM/BASICS/	/EQ 600MG BASE/	/N72362/001/ /JUN/16,/1988/
>DLT>				
>ADD>	ə PHARM BASICS	EQ 600MG BASE	N72362 001 JUN 16, 1988	
>ADD>				

FLUDARABINE PHOSPHATE

INJECTABLE; INJECTION
FLUDARA

	BERLEX	50MG/VIAL¤	N20038 001 APR 18, 1991

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL
/FLUOCET/

>DLT>				
>DLT>	/AT/	/NMC/	/0.01%/	/N88361/001/ /JAN/16,/1984/
>DLT>				

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL
FLUOCINOLONE ACETONIDE

> ADD >	AT	NMC	0.01%	N88361 001	
> ADD >				JAN 16, 1984	

FLUOXETINE HYDROCHLORIDE

SOLUTION; ORAL
PROZAC

LILLY	EQ 20MG BASE/5ML¤	N20101 001	
		APR 24, 1991	

> ADD > FOSINOPRIL SODIUM

> ADD > TABLET; ORAL
> ADD > MONOPRIL

> ADD >	BRISTOL MYERS SQUIBB	10MG¤	N19915 002
> ADD >			MAY 16, 1991
> ADD >		20MG¤	N19915 003
> ADD >			MAY 16, 1991

GALLIUM NITRATE

INJECTABLE; INJECTION
GANITE

FUJISAWA PHARM	25MG/ML¤	N19961 002
		JAN 17, 1991

GLUTETHIMIDE

TABLET; ORAL
/DORIDEN/

/AA/	/RHONE/POULENC/RORER/	/250MG/	/N09519/002/
/AA/		/500MG/	/N09519/005/
ə	RHONE POULENC RORER	250MG	N09519 002
ə		500MG	N09519 005

HALOBETASOL PROPIONATE

CREAM; TOPICAL
ULTRAVATE

/BRISTOL/MYERS/SQUIBB/	0.05%/	/N19967/001/
		/DEC/27,/1990/
WESTWOOD SQUIBB	0.05%	N19967 001
		DEC 27, 1990

HALOBETASOL PROPIONATE

OINTMENT; TOPICAL
ULTRAVATE

/BRISTOL/MYERS/SQUIBB/	0.05%/	/N19968/001/
		/DEC/17,/1990/
WESTWOOD SQUIBB	0.05%	N19968 001
		DEC 17, 1990

HALOPERIDOL LACTATE

INJECTABLE; INJECTION
HALOPERIDOL

/AP/	/LEMMON/	/EQ 5MG BASE/ML/		/N70713/001/
				/MAY/17,/1988/
/AP/		/EQ 5MG BASE/ML/		/N70714/001/
				/MAY/17,/1988/
/AP/		/EQ 5MG BASE/ML/		/N70744/001/
				/MAY/17,/1988/
AP	STERIS	EQ 5MG BASE/ML		N70713 001
				MAY 17, 1988
AP		EQ 5MG BASE/ML		N70714 001
				MAY 17, 1988
AP		EQ 5MG BASE/ML		N70744 001
				MAY 17, 1988

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN LOCK FLUSH

/AP/	/SOLOPAK/	/100 UNITS/ML/	/N87959/001/
			/APR/20,/1983/
ə	SOLOPAK	100 UNITS/ML	N87959 001
			APR 20, 1983

/HEPARIN SODIUM 10,000 UNITS IN DEXTROSE 5%/

/AP/	/ABBOTT/	/10,000 UNITS/100ML/	/N18911/006/
			/JAN/30,/1985/
ə	ABBOTT	10,000 UNITS/100ML	N18911 006
			JAN 30, 1985

HYDRALAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
HYDRALAZINE HCL

/AP/	/SOLOPAK/	/20MG/ML/	/N88517/001/
			/AUG/22,/1985/
ə	SOLOPAK	20MG/ML	N88517 001
			AUG 22, 1985

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

HYDRALAZINE HCL

> DLT >	/AA/	/CHELSEA/	/25MG/	/N85532/002/ /MAY/24,/1982/
> DLT >				
> DLT >	/AA/		/50MG/	/N85533/002/ /MAY/25,/1982/
> DLT >				
> ADD >		@ CHELSEA	25MG	N85532 002 MAY 24, 1982
> ADD >				
> ADD >		@	50MG	N85533 002 MAY 25, 1982
> ADD >				

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

HYDROCHLOROTHIAZIDE W/ RESERPINE

/BP/	/BOLAR/	/50MG;0.125MG/		/N83666/001/
	@ BOLAR	50MG;0.125MG		N83666 001

RESERPINE AND HYDROCHLOROTHIAZIDE

/BP/	/CORD/	/50MG;0.125MG/		/N88200/001/ /JAN/31,/1984/
	@ CORD	50MG;0.125MG		N88200 001 JAN 31, 1984

HYDROCHLOROTHIAZIDE; TRIAMTERENE

TABLET; ORAL

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

B*	PAR	50MG;75MG		N72337 001 MAY 11, 1988
/BX/		/50MG;75MG/		/N72337/001/ /MAY/11,/1988/

HYDROCORTISONE

CREAM; TOPICAL

/H-CORT/

/AT/	/PHARMS/ASSOC/	/0.5%/		/N86823/001/
	@ PHARMS ASSOC	0.5%		N86823 001

HYDROCORTISONE

/AT/	/WHITE/TOWNE/PAULSEN/	/1%/		/N80496/002/
	@ WHITE TOWNE PAULSEN	1%		N80496 002

/LOTION;/TOPICAL/

/TEXACORT/

/AT/	/COOPERCARE/	/1%/		/N80425/001/

HYDROCORTISONE

SOLUTION; TOPICAL

PENECORT

AT	HERBERT	1%		N88214 001 JUN 06, 1984

TEXACORT

AT	GENDERM	1%		N80425 001

TABLET; ORAL

HYDROCORTISONE

/BP/	/PUREPAC/	/20MG/		/N80395/001/
	@ PUREPAC	20MG		N80395 001

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OTIC

OTOCORT

/AT/	/LEMMON/	/1%;EQ 3.5MG BASE/ML;/ /10,000 UNITS/ML/		/N60730/002/
AT	STERIS	1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML		N60730 002

SUSPENSION; OTIC

OTOCORT

/AT/	/LEMMON/	/1%;EQ 3.5MG BASE/ML;/ /10,000 UNITS/ML/		/N62521/001/ /JUL/11,/1985/
AT	STERIS	1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML		N62521 001 JUL 11, 1985

HYDROCORTISONE ACETATE

INJECTABLE; INJECTION

HYDROCORTISONE ACETATE

/BP/	/LEMMON/	/25MG/ML/		/N83759/001/
/BP/		/50MG/ML/		/N83759/002/
BP	STERIS	25MG/ML		N83759 001
BP		50MG/ML		N83759 002

HYDROCORTISONE BUTYRATE

/CREAM;/TOPICAL/

/LOCOID/

	/OWEN/GALDERMA/	/0.1%/		/N18795/001/ /JAN/07,/1983/
	@ OWEN GALDERMA	0.1%		N18795 001 JAN 07, 1983

HYDROCORTISONE SODIUM SUCCINATE

INJECTABLE; INJECTION

		HYDROCORTISONE SODIUM SUCCINATE	
/AP/	/LYPHOMED/	/EQ 100MG BASE/VIAL/	/N88712/001/ /JUN/08,/1984/
/AP/		/EQ 250MG BASE/VIAL/	/N88668/001/ /JUN/08,/1984/
/AP/		/EQ 500MG BASE/VIAL/	/N88669/001/ /JUN/08,/1984/
/AP/		/EQ 1GM BASE/VIAL/	/N88670/001/ /JUN/08,/1984/
	@ LYPHOMED	EQ 100MG BASE/VIAL	N88712 001 JUN 08, 1984
	@	EQ 250MG BASE/VIAL	N88668 001 JUN 08, 1984
	@	EQ 500MG BASE/VIAL	N88669 001 JUN 08, 1984
	@	EQ 1GM BASE/VIAL	N88670 001 JUN 08, 1984

HYDROXOCOBALAMIN

INJECTABLE; INJECTION

		HYDROCOBALAMIN	
/AP/	/LEMMON/	/1MG/ML/	/N85528/001/
AP	STERIS	1MG/ML	N85528 001

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION

		HYDROXYZINE HCL	
/AP/	/LEMMON/	/25MG/ML/	/N87274/001/
/AP/		/50MG/ML/	/N87274/002/
AP	STERIS	25MG/ML	N87274 001
AP		50MG/ML	N87274 002

TABLET; ORAL

		HYDROXYZINE HCL	
/AB/	/BARR/	/10MG/	/N88409/001/ /NOV/15,/1983/
	@ BARR	10MG	N88409 001 NOV 15, 1983

HYDROXYZINE PAMOATE

CAPSULE; ORAL

		HYDROXYZINE PAMOATE	
/AB/	/VANGARD/	/EQ 25MG HCL/	/N88392/001/ /SEP/19,/1983/
	@ VANGARD	EQ 25MG HCL	N88392 001 SEP 19, 1983

IBUPROFEN

TABLET; ORAL

		IBUPROFEN		
>DLT> /BX/	/SUPERPHARM/	/400MG/	/N70708/001/ /APR/25,/1986/
>DLT>			

INDOMETHACIN

CAPSULE; ORAL

		INDOMETHACIN	
/AB/	/ROXANE/	/25MG/	/N70353/001/ /JUN/18,/1985/
/AB/		/50MG/	/N70354/001/ /JUN/18,/1985/
	@ ROXANE	25MG	N70353 001 JUN 18, 1985
	@	50MG	N70354 001 JUN 18, 1985

IOPAMIDOL

INJECTABLE; INJECTION

ISOVUE-M 200		
SQUIBB	41%	N18735 001 DEC 31, 1985
ISOVUE-200		
/SQUIBB/	/41%/	/N18735/001/ /DEC/31,/1985/
SQUIBB	41%*	N18735 006 JUL 07, 1987

ISONIAZID

TABLET; ORAL

		ISONIAZID		
>ADD>	AA	ZENITH	300MG	N83610 001

KETOCONAZOLE

SUSPENSION;ORAL
NIZORAL
JANSSEN | 100MG/5ML | N70767 001 | NOV 07, 1986

a JANSSEN | 100MG/5ML | N70767 001 NOV 07, 1986

LEVONORGESTREL

IMPLANT; IMPLANTATION
LEVONORGESTREL SYSTEM
WYETH AYERST | 36MG/IMPLANT | N20088 001 | DEC 10, 1990

NORPLANT SYSTEM
WYETH AYERST | 36MG/IMPLANT | N20088 001 | DEC 10, 1990

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
LIDOCAINE HCL
a/LEMMON | 1% | N83627 001
a | 2% | N83627 002

a STERIS | 1% | N83627 001
a | 2% | N83627 002

SOLUTION; TOPICAL
LIDOCAINE HCL
> DLT > AT PACO | 4% | N89688 001 | JUN 30, 1989
> ADD >

a PACO | 4% | N89688 001 JUN 30, 1989

LINCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION
LINCOMYCIN HCL
AP STERIS | EQ 300MG BASE/ML¤ | N63180 001 APR 16, 1991

LITHIUM CARBONATE

CAPSULE; ORAL
LITHIUM CARBONATE
AB PHARM BASICS | 300MG | N72542 001 | FEB 01, 1989

AB PHARM BASICS | 300MG | N72542 001 FEB 01, 1989

LORAZEPAM

TABLET; ORAL
LORAZEPAM
BX AM THERAP | 0.5MG | N70727 001 | MAR 07, 1986
BX | 1MG | N70728 001 | MAR 07, 1986
BX | 2MG | N70729 001 | MAR 07, 1986

a AM THERAP | 0.5MG | N70727 001 MAR 07, 1986
a | 1MG | N70728 001 MAR 07, 1986
a | 2MG | N70729 001 MAR 07, 1986

AB MUTUAL PHARM | 0.5MG¤ | N72553 001 MAR 29, 1991
AB | 1MG¤ | N72554 001 MAR 29, 1991
AB | 2MG¤ | N72555 001 MAR 29, 1991

LOVASTATIN

TABLET; ORAL
MEVACOR
MSD | 10MG¤ | N19643 002 MAR 28, 1991

MANNITOL

INJECTABLE; INJECTION
MANNITOL 10%
AP CUTTER | 10GM/100ML | N16472 002
a CUTTER | 10GM/100ML | N16472 002

MANNITOL 15%
AP CUTTER | 15GM/100ML | N16472 005
a CUTTER | 15GM/100ML | N16472 005

MANNITOL

INJECTABLE; INJECTION
MANNITOL 20%

/AP/	/CUTTER/	/20GM/100ML/	/N16472/004/
	ə CUTTER	20GM/100ML	N16472 004

MEGESTROL ACETATE

TABLET; ORAL
MEGESTROL ACETATE

B*	PHARM BASICS	20MG	N70646 001 OCT 02, 1987
B*		40MG	N70647 001 OCT 02, 1987
/BX/		/20MG/	/N70646/001/ /OCT/02,/1987/
/BX/		/40MG/	/N70647/001/ /OCT/02,/1987/

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
MEPERIDINE HCL

/AP/	/ELKINS/SINN/	/25MG/ML/	/N88279/001/ /JUN/15,/1984/
/AP/		/50MG/ML/	/N88280/001/ /JUN/15,/1984/
/AP/		/75MG/ML/	/N88281/001/ /JUN/15,/1984/
/AP/		/100MG/ML/	/N88282/001/ /JUN/15,/1984/
	ə ELKINS SINN	25MG/ML	N88279 001 JUN 15, 1984
	ə	50MG/ML	N88280 001 JUN 15, 1984
	ə	75MG/ML	N88281 001 JUN 15, 1984
	ə	100MG/ML	N88282 001 JUN 15, 1984

METAPROTERENOL SULFATE

TABLET; ORAL
METAPROTERENOL SULFATE

/AB/	/AM/THERAP/	/10MG/	/N72054/001/ /JUN/23,/1988/
/AB/		/20MG/	/N72055/001/ /JUN/23,/1988/
	ə AM THERAP	10MG	N72054 001 JUN 23, 1988
	ə	20MG	N72055 001 JUN 23, 1988
AB	DANBURY	10MG*	N73013 001 JAN 31, 1991
AB		20MG*	N72795 001 JAN 31, 1991
/AB/	/PHARM/BASICS/	/10MG/	/N71013/001/ /JAN/25,/1988/
/AB/		/20MG/	/N71014/001/ /JAN/25,/1988/
B*	PHARM BASICS	10MG	N71013 001 JAN 25, 1988
B*		20MG	N71014 001 JAN 25, 1988

METHADONE HYDROCHLORIDE

/TABLET;/EFFERVESCENT;/ORAL/

	/WESTADONE/ /VITARINE/	/2.5MG/	/N17108/001/
		/5MG/	/N17108/002/
		/10MG/	/N17108/003/
		/40MG/	/N17108/004/
	ə VITARINE	2.5MG	N17108 001
	ə	5MG	N17108 002
	ə	10MG	N17108 003
	ə	40MG	N17108 004

METHYLPREDNISOLONE ACETATE

INJECTABLE; INJECTION
METHYLPREDNISOLONE ACETATE

/ə/	/LEMMON/	/20MG/ML/	/N87248/001/
/ə/		/40MG/ML/	/N85374/001/
/ə/		/80MG/ML/	/N86507/001/
	ə STERIS	20MG/ML	N87248 001
	ə	40MG/ML	N85374 001
	ə	80MG/ML	N86507 001

METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION

A-METHAPRED

AP	ABBOTT	EQ 40MG BASE/VIAL¤	N89573 001 FEB 22, 1991
AP		EQ 125MG BASE/VIAL¤	N89574 001 FEB 22, 1991
AP		EQ 500MG BASE/VIAL¤	N89575 001 FEB 22, 1991
AP		EQ 1GM BASE/VIAL¤	N89576 001 FEB 22, 1991

METHYLPREDNISOLONE SODIUM SUCCINATE

/AP/	/LYPHOMED/	/EQ 40MG BASE/VIAL/	/N88676/001/ /JUN/08,/1984/
/AP/		/EQ 125MG BASE/VIAL/	/N88677/001/ /JUN/08,/1984/
/AP/		/EQ 500MG BASE/VIAL/	/N88678/001/ /JUN/08,/1984/
/AP/		/EQ 500MG BASE/VIAL/	/N89186/001/ /MAR/28,/1986/
/AP/		/EQ 1GM BASE/VIAL/	/N88679/001/ /JUN/08,/1984/
/AP/		/EQ 1GM BASE/VIAL/	/N89188/001/ /MAR/28,/1986/
	@ LYPHOMED	EQ 40MG BASE/VIAL	N88676 001 JUN 08, 1984
	@	EQ 125MG BASE/VIAL	N88677 001 JUN 08, 1984
	@	EQ 500MG BASE/VIAL	N88678 001 JUN 08, 1984
	@	EQ 500MG BASE/VIAL	N89186 001 MAR 28, 1986
	@	EQ 1GM BASE/VIAL	N88679 001 JUN 08, 1984
	@	EQ 1GM BASE/VIAL	N89188 001 MAR 28, 1986

METHYLTESTOSTERONE

TABLET; BUCCAL/SUBLINGUAL

METHYLTESTOSTERONE

> DLT >	/BP/	/PHARM/BASICS/	/10MG/	/N80271/001/
> ADD >		@ PHARM BASICS	10MG	N80271 001

METHYPRYLON

TABLET; ORAL

NOLUDAR

	/ROCHE/	/50MG/	/N09660/002/
	@ ROCHE	50MG	N09660 002

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

METOCLOPRAMIDE HCL

AP	ABBOTT	EQ 10MG BASE/2ML¤	N73117 001 JAN 17, 1991
AP		EQ 10MG BASE/2ML¤	N73118 001 JAN 17, 1991

SYRUP; ORAL

METOCLOPRAMIDE HCL

> ADD >	AA	PHARMS ASSOC	EQ 5MG BASE/5ML¤	N72744 001 MAY 28, 1991
> ADD >				

TABLET; ORAL

METOCLOPRAMIDE HCL

> ADD >	AB	LEDERLE	EQ 10MG BASE¤	N72639 001 MAY 09, 1991
> ADD >				
> DLT >	/AB/	/MARTEC/	/EQ 10MG BASE/	/N70598/001/ /FEB/02,/1987/
> DLT >				
> ADD >	AB	SCHERING	EQ 10MG BASE	N70598 001 FEB 02, 1987
> ADD >				

METRONIDAZOLE

INJECTABLE; INJECTION

METRONIDAZOLE

AP	STERIS	500MG/100ML	N70042 001 DEC 20, 1984

METRYL IV

/AP/	/STERIS/	/500MG/100ML/	/N70042/001/ /DEC/20,/1984/

MICONAZOLE NITRATE

/CREAM;/VAGINAL/

/MONISTAT 7/

/AT/	/JOHNSON/RW/	/2%/	/N17456/001/

/SUPPOSITORY;/VAGINAL/

/MONISTAT 7/

/AT/	/JOHNSON/RW/	/100MG/	/N18526/001/ /MAR/15,/1982/

MINOXIDIL

TABLET; ORAL
MINOXIDIL

/AB/	/PHARM/BASICS/	/2.5MG/	/N71537/001/ /DEC/16,/1988/	
B*	PHARM BASICS	2.5MG	N71537 001 DEC 16, 1988	

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION
NALOXONE

/AP/	/ELKINS/SINN/	/0.4MG/ML/	/N70496/001/ /OCT/22,/1985/	
	@ ELKINS SINN	0.4MG/ML	N70496 001 OCT 22, 1985	

NANDROLONE DECANOATE

INJECTABLE; INJECTION
NANDROLONE DECANOATE

/AO/	/LEMMON/	/50MG/ML/	/N87598/001/ /OCT/06,/1983/	
/AO/		/50MG/ML/	/N88554/001/ /FEB/10,/1986/	
/AO/		/100MG/ML/	/N87599/001/ /OCT/06,/1983/	
AO	STERIS	50MG/ML	N87598 001 OCT 06, 1983	
AO		50MG/ML	N88554 001 FEB 10, 1986	
AO		100MG/ML	N87599 001 OCT 06, 1983	

NIACIN

TABLET; ORAL
NIACIN

/AA/	/WEST/WARD/	/500MG/	/N83718/001/	
	@ WEST WARD	500MG	N83718 001	

NITROGLYCERIN

INJECTABLE; INJECTION
/NITROL/

/AP/	/KREMERS/URBAN/	/0.8MG/ML/	/N18774/001/ /JAN/19,/1983/	

NITROGLYCERIN

INJECTABLE; INJECTION
/NITROL/

	@ RORER	0.8MG/ML	N18774 001 JAN 19, 1983	

NITROSTAT

/AP/	/PARKE/DAVIS/	/0.8MG/ML/	/N18588/001/	
	PARKE DAVIS	0.8MG/ML	N18588 001	

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION
ZOFRAN

GLAXO	EQ 2MG BASE/ML*	N20007 001 JAN 04, 1991	

OXAZEPAM

CAPSULE; ORAL
OXAZEPAM

B*	CHELSEA	10MG	N71661 001 MAR 02, 1988	
B*		15MG	N71662 001 MAR 02, 1988	
B*		30MG	N71663 001 MAR 02, 1988	
/BX/		/10MG/	/N71661/001/ /MAR/02,/1988/	
/BX/		/15MG/	/N71662/001/ /MAR/02,/1988/	
/BX/		/30MG/	/N71663/001/ /MAR/02,/1988/	

PERPHENAZINE

TABLET; ORAL
PERPHENAZINE

B*	CHELSEA	8MG	N89700 001 DEC 23, 1987	
/BX/		/8MG/	/N89700/001/ /DEC/23,/1987/	

PHENDIMETRAZINE TARTRATE

CAPSULE, EXTENDED RELEASE; ORAL
PHENDIMETRAZINE TARTRATE

>ADD> >DLT>	BC	VITARINE	105MG	N18074 001	
	/S/		/105MG/	/N18074/001/	

PHENDIMETRAZINE TARTRATE

CAPSULE, EXTENDED RELEASE; ORAL

> DLT >		/SPRX-105/		
> DLT >	/BC/	/REID/ROWELL/	/105MG/	/N88024/001/ /DEC/22,/1982/
> DLT >				
> ADD >		∂ REID ROWELL	105MG	N88024 001 DEC 22, 1982
> ADD >				

TABLET; ORAL

PHENDIMETRAZINE TARTRATE

/AA/	/CORD/	/35MG/	/N86365/001/
	∂ CORD	35MG	N86365 001

PIPERAZINE CITRATE

SYRUP; ORAL

PIPERAZINE CITRATE

/AA/	/BARRE/	/EQ 500MG BASE/5ML/	/N80774/001/
	∂ BARRE	EQ 500MG BASE/5ML	N80774 001

POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE

POWDER FOR RECONSTITUTION; ORAL

	NULYTELY		
	BRAINTREE	420GM/BOT;1.48GM/BOT;5.72GM/BOT; 11.2GM/BOT¤	N19797 001 APR 22, 1991

POTASSIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE

/AP/	/ELKINS/SINN/	/2MEQ/ML/	/N80203/001/
	∂ ELKINS SINN	2MEQ/ML	N80203 001
/AP/	/LEMMON/	/2MEQ/ML/	/N86208/001/
/AP/		/3MEQ/ML/	/N86210/001/
/AP/	/LILLY/	/2MEQ/ML/	/N07865/002/
	∂ LILLY	2MEQ/ML	N07865 002
AP	STERIS	2MEQ/ML	N86208 001
AP		3MEQ/ML	N86210 001

PRAZEPAM

CAPSULE; ORAL

PRAZEPAM

/AB/	/PHARM/BASICS/	/5MG/	/N70427/001/ /NOV/06,/1987/
/AB/		/10MG/	/N70428/001/ /NOV/06,/1987/
B*	PHARM BASICS	5MG	N70427 001 NOV 06, 1987
B*		10MG	N70428 001 NOV 06, 1987

PREDNISOLONE ACETATE

INJECTABLE; INJECTION

PREDNISOLONE ACETATE

/BP/	/CENTRAL/PHARMS/	/25MG/ML/	/N84717/001/
	∂ CENTRAL PHARMS	25MG/ML	N84717 001
/BP/	/LEMMON/	/25MG/ML/	/N83654/001/
/BP/		/50MG/ML/	/N85781/001/
BP	STERIS	25MG/ML	N83654 001
BP		50MG/ML	N85781 001

PREDNISONE

TABLET; ORAL

PREDNISONE

/BX/	/AM/THERAP/	/5MG/	/N89387/001/ /NOV/06,/1986/
/BX/		/10MG/	/N89388/001/ /NOV/06,/1986/
/BX/		/20MG/	/N89389/001/ /NOV/06,/1986/
	∂ AM THERAP	5MG	N89387 001 NOV 06, 1986
	∂	10MG	N89388 001 NOV 06, 1986
	∂	20MG	N89389 001 NOV 06, 1986

PREDNISONE

TABLET; ORAL

	PREDNISONE		
/AB/	/ROXANE/	/1MG/	/N87800/001/ /APR/22,/1982/
/AB/		/2.5MG/	/N87801/001/ /APR/22,/1982/
/AB/		/10MG/	/N84122/001/
/AB/		/20MG/	/N87342/001/
/AB/		/50MG/	/N84283/001/
	ə ROXANE	1MG	N87800 001 APR 22, 1982
	ə	2.5MG	N87801 001 APR 22, 1982
	ə	10MG	N84122 001
	ə	20MG	N87342 001
	ə	50MG	N84283 001

PROCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

	PROCAINE HCL		
/AP/	/LEMMON/	/1%/	/N83535/001/
/AP/		/2%/	/N83535/002/
AP	STERIS	1%	N83535 001
AP		2%	N83535 002

PROCHLORPERAZINE EDISYLATE

	/CONCENTRATE;/ORAL/		
> DLT >	/PROCHLORPERAZINE/EDISYLATE/		
> DLT >	/PHARM/BASICS/	/EQ/10MG/BASE/ML/	/N88598/001/ /OCT/25,/1984/
> ADD >	ə PHARM BASICS	EQ 10MG BASE/ML	N88598 001 OCT 25, 1984

SYRUP; ORAL

	COMPAZINE		
> DLT >/AA/	/SKF/	/EQ 5MG BASE/5ML/	/N11188/001/
> ADD >	SKF	EQ 5MG BASE/5ML	N11188 001

	PROCHLORPERAZINE EDISYLATE		
> DLT >/AA/	/PHARM/BASICS/	/EQ 5MG BASE/5ML/	/N88597/001/ /OCT/25,/1984/
> ADD >	ə PHARM BASICS	EQ 5MG BASE/5ML	N88597 001 OCT 25, 1984

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

	PROMETHAZINE HCL		
/AP/	/LEMMON/	/25MG/ML/	/N83532/001/
/AP/		/50MG/ML/	/N83532/002/
AP	STERIS	25MG/ML	N83532 001
AP		50MG/ML	N83532 002

PROPRANOLOL HYDROCHLORIDE

SOLUTION; ORAL

	PROPRANOLOL HCL		
> DLT >/AA/	/PHARM/BASICS/	/20MG/5ML/	/N71984/001/ /MAR/03,/1989/
> DLT >			
> DLT >/AA/		/40MG/5ML/	/N71985/001/ /MAR/03,/1989/
> ADD >	ə PHARM BASICS	20MG/5ML	N71984 001 MAR 03, 1989
> ADD >	ə	40MG/5ML	N71985 001 MAR 03, 1989
> DLT >/AA/	/ROXANE/	/20MG/5ML/	/N70979/001/ /MAY/15,/1987/
> DLT >			
> DLT >/AA/		/40MG/5ML/	/N70690/001/ /MAY/15,/1987/
> ADD >	ROXANE	20MG/5ML	N70979 001 MAY 15, 1987
> ADD >		40MG/5ML	N70690 001 MAY 15, 1987

TABLET; ORAL

	PROPRANOLOL HCL		
> DLT >/AB/	/MARTEC/	/10MG/	/N70120/001/ /AUG/06,/1985/
> DLT >			
> DLT >/AB/		/20MG/	/N70121/001/ /AUG/06,/1985/
> DLT >			
> DLT >/AB/		/40MG/	/N70122/001/ /AUG/06,/1985/
> DLT >			
> DLT >/AB/		/60MG/	/N70123/001/ /OCT/29,/1986/
> DLT >			
> DLT >/AB/		/80MG/	/N70124/001/ /AUG/06,/1985/
> ADD > AB	SCHERING	10MG	N70120 001 AUG 06, 1985
> ADD >			
> ADD > AB		20MG	N70121 001 AUG 06, 1985
> ADD >			
> ADD > AB		40MG	N70122 001 AUG 06, 1985
> ADD >			
> ADD > AB		60MG	N70123 001 OCT 29, 1986
> ADD >			
> ADD > AB		80MG	N70124 001 AUG 06, 1985
> ADD >			

PYRIDOSTIGMINE BROMIDE

TABLET; ORAL
PYRIDOSTIGMINE BROMIDE

KALI DUPHAR	30MG	N89572 001	NOV 27, 1990
/PUREPAC/	/30MG/	/N89572/001/	/NOV/27,/1990/

PYRIDOXINE HYDROCHLORIDE

INJECTABLE; INJECTION
PYRIDOXINE HCL

/AP/ /LEMMON/	/100MG/ML/	/N83760/001/	
AP STERIS	100MG/ML	N83760 001	

PYRILAMINE MALEATE

TABLET; ORAL
PYRILAMINE MALEATE

/AA/ /CHELSEA/	/25MG/	/N85231/001/	
ə CHELSEA	25MG	N85231 001	
/AA/ /RICHLYN/	/25MG/	/N80808/001/	
RICHLYN	25MG	N80808 001	

QUINIDINE SULFATE

TABLET; ORAL
QUINIDINE SULFATE

/AB/ /VANGARD/	/200MG/	/N87909/001/	/JUL/13,/1982/
ə VANGARD	200MG	N87909 001	JUL 13, 1982

QUINORA

/AB/ /KEY/PHARMS/	/200MG/	/N83576/001/	
ə KEY PHARMS	200MG	N83576 001	

RAMIPRIL

CAPSULE; ORAL
ALTACE

HOECHST ROUSSEL	1.25MG¤	N19901 001	JAN 28, 1991
	2.5MG¤	N19901 002	JAN 28, 1991
	5MG¤	N19901 003	JAN 28, 1991
	10MG¤	N19901 004	JAN 28, 1991

RESERPINE

TABLET; ORAL
RESERPINE

/BP/ /WHITE/TOWNE/PAULSEN/	/0.1MG/	/N80723/001/	
/BP/	/0.25MG/	/N80723/002/	
ə WHITE TOWNE PAULSEN	0.1MG	N80723 001	
ə	0.25MG	N80723 002	
	/1MG/	/N80723/003/	
ə	1MG	N80723 003	

RITODRINE HYDROCHLORIDE

INJECTABLE; INJECTION
RITODRINE HCL

AP ABBOTT	10MG/ML¤	N71618 001	FEB 28, 1991
AP	15MG/ML¤	N71619 001	FEB 28, 1991

RITODRINE HCL IN DEXTROSE 5% IN PLASTIC CONTAINER

ABBOTT	30MG/100ML¤	N71438 001	JAN 22, 1991

SECOBARBITAL SODIUM

CAPSULE; ORAL
SECOBARBITAL SODIUM

>DLT >/AA/ /WYETH/AYERST/	/100MG/	/N86390/001/		
>ADD > ə WYETH AYERST	100MG	N86390 001		

SELENIUM SULFIDE

LOTION/SHAMPOO; TOPICAL
SELENIUM SULFIDE

AT CLAY PARK	2.5%¤	N89996 001	JAN 10, 1991

SODIUM NITROPRUSSIDE

INJECTABLE; INJECTION
SODIUM NITROPRUSSIDE

/AP/ /LYPHOMED/	/50MG/VIAL/	/N70031/001/	/JAN/17,/1985/
ə LYPHOMED	50MG/VIAL	N70031 001	JAN 17, 1985

SUCCIMER

CAPSULE; ORAL
CHEMET
MCNEIL 100MG¤ N19998 002 JAN 30, 1991

SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION
COTRIM
/AP/ /STERIS/ /80MG/ML;16MG/ML/ /N71556/001/ /DEC/17,/1987/

SULFAMETHOXAZOLE AND TRIMETHOPRIM
AP STERIS 80MG/ML;16MG/ML N71556 001 DEC 17, 1987

SULINDAC

TABLET; ORAL
SULINDAC
AB MUTUAL PHARM 150MG¤ N72050 001 APR 17, 1991
AB 200MG¤ N72051 001 APR 17, 1991
AB WARNER CHILCOTT 150MG¤ N72710 001 MAR 25, 1991
AB 200MG¤ N72711 001 MAR 25, 1991

TERCONAZOLE

CREAM; VAGINAL
TERAZOL 3
JOHNSON RW 0.8%¤ N19964 001 FEB 21, 1991

TESTOSTERONE CYPIONATE

INJECTABLE; INJECTION
TESTOSTERONE CYPIONATE
/AO/ /LEMMON/ /100MG/ML/ /N84401/001/
/AO/ /200MG/ML/ /N84401/002/
AO STERIS 100MG/ML N84401 001
AO 200MG/ML N84401 002

TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION
TESTOSTERONE ENANTHATE
/AO/ /LEMMON/ /100MG/ML/ /N83667/001/
/AO/ /200MG/ML/ /N83667/002/
AO STERIS 100MG/ML N83667 001
AO 200MG/ML N83667 002

TESTOSTERONE PROPIONATE

INJECTABLE; INJECTION
TESTOSTERONE PROPIONATE
/AO/ /LEMMON/ /25MG/ML/ /N85490/001/
/AO/ /50MG/ML/ /N85490/002/
/AO/ /100MG/ML/ /N83595/003/
AO STERIS 25MG/ML N85490 001
AO 50MG/ML N85490 002
AO 100MG/ML N83595 003

THEOPHYLLINE

CAPSULE; ORAL
>DLT> /SOMOPHYLLIN-T/
>DLT> /BX/ /FISONS/ /100MG/ /N87155/001/ /FEB/25,/1985/
>DLT> /BX/ /200MG/ /N87155/002/ /FEB/25,/1985/
>DLT> /BX/ /250MG/ /N87155/003/ /FEB/25,/1985/
>ADD> @ FISONS 100MG N87155 001 FEB 25, 1985
>ADD> @ 200MG N87155 002 FEB 25, 1985
>ADD> @ 250MG N87155 003 FEB 25, 1985

THEOPHYLLINE
>DLT> /BX/ /SCHERER/ /100MG/ /N84731/002/ /NOV/07,/1986/
>DLT> /BX/ /200MG/ /N84731/001/ /NOV/07,/1986/
>DLT> /BX/ /250MG/ /N84731/003/ /NOV/07,/1986/
>ADD> @ SCHERER 100MG N84731 002 NOV 07, 1986
>ADD> @ 200MG N84731 001 NOV 07, 1986
>ADD> @ 250MG N84731 003 NOV 07, 1986

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL

THEOPHYLLINE

/BC/	/CENTRAL/PHARMS/	/125MG/	/N88654/001/ FEB/12,/1985/		
/BC/		/250MG/	/N88689/001/ FEB/12,/1985/		
	@ CENTRAL PHARMS	125MG	N88654 001 FEB 12, 1985		
	@	250MG	N88689 001 FEB 12, 1985		

THEOPHYLLINE-SR

>DLT> /BC/	/SCHERER/	/300MG/	/N88255/001/ JUN/12,/1986/		
>DLT>					
>ADD>	@ SCHERER	300MG	N88255 001 JUN 12, 1986		
>ADD>					

TABLET; ORAL

THEOCLEAR-100

/BD/	/CENTRAL/PHARMS/	/100MG/	/N85353/002/
	@ CENTRAL PHARMS	100MG	N85353 002

THEOCLEAR-200

/BD/	/CENTRAL/PHARMS/	/200MG/	/N85353/001/
	@ CENTRAL PHARMS	200MG	N85353 001

THIAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

THIAMINE HCL

/AP/	/LEMMON/	/100MG/ML/	/N83534/001/
/AP/		/200MG/ML/	/N83534/002/
/AP/	/LYPHOMED/	/100MG/ML/	/N80509/001/
	@ LYPHOMED	100MG/ML	N80509 001
AP	STERIS	100MG/ML	N83534 001
AP		200MG/ML	N83534 002

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL

THIORIDAZINE HCL

/AB/	/ROXANE/	/10MG/	/N88663/001/ MAR/15,/1984/	
/AB/		/25MG/	/N88664/001/ MAR/15,/1984/	
/AB/		/50MG/	/N88665/001/ MAR/15,/1984/	
/AB/		/100MG/	/N89048/001/ FEB/26,/1985/	
	@ ROXANE	10MG	N88663 001 MAR 15, 1984	
	@	25MG	N88664 001 MAR 15, 1984	
	@	50MG	N88665 001 MAR 15, 1984	
	@	100MG	N89048 001 FEB 26, 1985	

THIOTHIXENE

CAPSULE; ORAL

THIOTHIXENE

>DLT> /AB/	/AM/THERAP/	/1MG/	/N71884/001/ AUG/12,/1987/	
>DLT> /AB/		/2MG/	/N71885/001/ AUG/12,/1987/	
>DLT> /AB/		/10MG/	/N71887/001/ AUG/12,/1987/	
>DLT>				
>ADD>	@ AM THERAP	1MG	N71884 001 AUG 12, 1987	
>ADD>	@	2MG	N71885 001 AUG 12, 1987	
>ADD>	@	10MG	N71887 001 AUG 12, 1987	

THIOTHIXENE HYDROCHLORIDE

CONCENTRATE; ORAL

THIOTHIXENE HCL

>DLT> /AA/	/PACO/	/EQ 5MG BASE/ML/	/N71939/001/ DEC/16,/1988/	
>DLT>				
>DLT>		/EQ 1MG/BASE/ML/	/N71917/001/ SEP/20,/1989/	
>DLT>				
>ADD>	@ PACO	EQ 5MG BASE/ML	N71939 001 DEC 16, 1988	
>ADD>				
>ADD>		EQ 1MG BASE/ML	N71917 001 SEP 20, 1989	
>ADD>				

TIMOLOL MALEATE

TABLET; ORAL

TIMOLOL MALEATE

/AB/	/PHARM/BASICS/	/5MG/	/N72001/001/ /JAN/10,/1989/	
/AB/		/10MG/	/N72002/001/ /JAN/10,/1989/	
/AB/		/20MG/	/N72003/001/ /JAN/10,/1989/	
B*	PHARM BASICS	5MG	N72001 001 JAN 10, 1989	
B*		10MG	N72002 001 JAN 10, 1989	
B*		20MG	N72003 001 JAN 10, 1989	

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION

TOBRAMYCIN SULFATE

AP	ABBOTT	EQ 10MG BASE/ML¤	N63080 001 APR 30, 1991	
AP		EQ 10MG BASE/ML¤	N63112 001 APR 30, 1991	
AP		EQ 40MG BASE/ML¤	N63111 001 APR 30, 1991	
> ADD > AP		EQ 40MG BASE/ML¤	N63161 001 MAY 29, 1991	
> ADD > AP	LEDERLE	EQ 10MG BASE/ML¤	N63113 001 APR 26, 1991	
AP		EQ 40MG BASE/ML¤	N63117 001 APR 26, 1991	

TOLAZAMIDE

TABLET; ORAL

TOLAZAMIDE

/AB/	/CHELSEA/	/100MG/	/N70285/001/ /JAN/09,/1986/	
/AB/		/250MG/	/N70286/001/ /JAN/09,/1986/	
/AB/		/500MG/	/N70287/001/ /JAN/09,/1986/	
B*	CHELSEA	100MG	N70285 001 JAN 09, 1986	
B*		250MG	N70286 001 JAN 09, 1986	
B*		500MG	N70287 001 JAN 09, 1986	

TRAZODONE HYDROCHLORIDE

TABLET; ORAL

TRAZODONE HCL

/AB/	/CHELSEA/	/50MG/	/N70568/001/ /OCT/10,/1986/	
/AB/		/100MG/	/N70569/001/ /OCT/10,/1986/	
B*	CHELSEA	50MG	N70568 001 OCT 10, 1986	
B*		100MG	N70569 001 OCT 10, 1986	
AB	MYLAN	50MG¤	N71405 001 FEB 27, 1991	
AB		100MG¤	N71406 001 FEB 27, 1991	

TRETINOIN

GEL; TOPICAL

RETIN-A

> DLT >/AT/	/JOHNSON/RW/	/0.01%/	/N17579/003/	

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

TRIAMCINOLONE ACETONIDE

> ADD > AT	G AND W	0.025%¤	N89797 001 MAY 31, 1991	
> ADD > AT		0.1%¤	N89798 001 MAY 31, 1991	
> DLT >/AT/	/PHARM/BASICS/	/0.025%/	/N88094/001/ /SEP/01,/1983/	
> DLT >/AT/		/0.1%/	/N88095/001/ /SEP/01,/1983/	
> DLT >/AT/		/0.5%/	/N88096/001/ /SEP/01,/1983/	
> ADD >	@ PHARM BASICS	0.025%	N88094 001 SEP 01, 1983	
> ADD >	@	0.1%	N88095 001 SEP 01, 1983	
> ADD >	@	0.5%	N88096 001 SEP 01, 1983	

/GEL;/TOPICAL/ /ARISTOGEL/ /LEDERLE/ /0.1%/ /N83380/001/

@ LEDERLE 0.1% N83380 001

TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL
ARISTOCORT A
/AT/ /LEDERLE/ /0.5%/ /N88781/001/ /OCT/05,/1984/
@ LEDERLE 0.5% N88781 001 OCT 05, 1984

TRIAMCINOLONE ACETONIDE
>DLT >/AT/ /PHARM/BASICS/ /0.025%/ /N88090/001/ /SEP/01,/1983/
>DLT >
>DLT >/AT/ /0.1%/ /N88091/001/ /SEP/01,/1983/
>DLT >
>DLT >/AT/ /0.5%/ /N88092/001/ /SEP/01,/1983/
>DLT >
>ADD > @ PHARM BASICS 0.025% N88090 001 SEP 01, 1983
>ADD >
>ADD > @ 0.1% N88091 001 SEP 01, 1983
>ADD >
>ADD > @ 0.5% N88092 001 SEP 01, 1983
>ADD >

TRIAMCINOLONE DIACETATE

INJECTABLE; INJECTION
TRIAMCINOLONE DIACETATE
/BP/ /LEMMON/ /40MG/ML/ /N85529/001/
BP STERIS 40MG/ML N85529 001

TRIMEPRAZINE TARTRATE

SYRUP; ORAL
TEMARIL
>DLT >/AA/ /HERBERT/ /EQ 2.5MG BASE/5ML/ /N11316/003/
>ADD > HERBERT EQ 2.5MG BASE/5ML N11316 003
>DLT > /TRIMEPRAZINE TARTRATE/
>DLT >/AA/ /PHARM/BASICS/ /EQ 2.5MG BASE/5ML/ /N88285/001/ /APR/11,/1985/
>DLT >
>ADD > @ PHARM BASICS EQ 2.5MG BASE/5ML N88285 001 APR 11, 1985
>ADD >

TRIMIPRAMINE MALEATE

CAPSULE; ORAL
TRIMIPRAMINE MALEATE
/AB/ /PHARM/BASICS/ /EQ 25MG BASE/ /N71283/001/ /DEC/08,/1987/
/AB/ /EQ 50MG BASE/ /N71284/001/ /DEC/08,/1987/
/AB/ /EQ 100MG BASE/ /N71285/001/ /DEC/08,/1987/
B* PHARM BASICS EQ 25MG BASE N71283 001 DEC 08, 1987
B* EQ 50MG BASE N71284 001 DEC 08, 1987
B* EQ 100MG BASE N71285 001 DEC 08, 1987

VERAPAMIL HYDROCHLORIDE

INJECTABLE; INJECTION
/CALAN/
/AP/ /SEARLE/ /2.5MG/ML/ /N18925/001/ /MAR/30,/1984/
@ SEARLE 2.5MG/ML N18925 001 MAR 30, 1984

TABLET; ORAL
VERAPAMIL HCL
B* CHELSEA 80MG N70421 001 SEP 17, 1986
B* 120MG N70422 001 SEP 17, 1986
/BX/ /80MG/ /N70421/001/ /SEP/17,/1986/
/BX/ /120MG/ /N70422/001/ /SEP/17,/1986/

TABLET, EXTENDED RELEASE; ORAL
ISOPTIN SR
KNOLL 120MG# N19152 003 MAR 06, 1991

CHLORHEXIDINE GLUCONATE

SOLUTION; TOPICAL
MICRODERM
JOHNSON AND JOHNSON 4%¤ N72255 001
APR 15, 1991

SPONGE; TOPICAL
MICRODERM
JOHNSON AND JOHNSON 4%¤ N72295 001
FEB 28, 1991

DOXYLAMINE SUCCINATE

> ADD >
> ADD >
> ADD >
> ADD >
TABLET; ORAL
DOXYLAMINE SUCCINATE
COPLEY 25MG¤ N88900 002
FEB 12, 1988

HYDROCORTISONE

/OINTMENT;TOPICAL/
/HC/(HYDROCORTISONE)/
/C/AND/M/
@ C AND M /0.5%/ 0.5% /N80481/001/ N80481 001

MICONAZOLE NITRATE

CREAM; VAGINAL
MONISTAT 7
JOHNSON RW 2%¤ N17450 002
FEB 15, 1991

SUPPOSITORY; VAGINAL
MONISTAT 7
JOHNSON RW 100MG¤ N18520 002
FEB 15, 1991

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE DIVISION OF BLOOD AND BLOOD PRODUCTS LIST
CUMULATIVE SUPPLEMENT NUMBER 4 / JAN '91 - APR '91

HETASTARCH 6% IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

INJECTABLE; INJECTION
HESPAN
DUPONT MERCK
PHARM — 6GM/100ML;0.9GM/100ML — N890105
APR 04, 1991

PENTASTARCH 10% IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

INJECTABLE; INJECTION
PENTASPAN
DUPONT MERCK
PHARM — 10GM/100ML;0.9GM/100ML — N890104
APR 04, 1991

ORPHAN DRUG PRODUCT DESIGNATIONS

SECTION 526 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT CONTAINS PROVISIONS WHEREBY FDA MAY DESIGNATE A SPONSOR'S DRUG, ANTIBIOTIC, OR BIOLOGICAL PRODUCT AS A "DESIGNATED ORPHAN DRUG." SECTION 527 OF THE ACT ESTABLISHES A PROCESS WHEREBY A SPONSOR MAY RECEIVE SEVEN YEARS OF EXCLUSIVE APPROVAL STATUS IF THAT SPONSOR IS THE FIRST TO ACHIEVE NEW DRUG, ANTIBIOTIC, OR BIOLOGICAL PRODUCT APPROVAL FOR A DESIGNATED ORPHAN DRUG FOR THE DESIGNATED INDICATION(S). THE EXCLUSIVE APPROVAL MAY BE REVOKED BY WRITTEN CONSENT OF THE SPONSOR OR BY FDA ACTION AFTER FINDING THAT THE SPONSOR HOLDING EXCLUSIVE APPROVAL CANNOT ASSURE THE AVAILABILITY OF SUFFICIENT QUANTITIES OF THE DRUG TO MEET THE NEEDS OF PATIENTS WITH THE DESIGNATED ORPHAN INDICATION(S).

WHEN A PRODUCT IS GRANTED ORPHAN DRUG DESIGNATION, IT WILL APPEAR IN THIS SECTION. ONCE A BIOLOGICAL OR DRUG PRODUCT IS LICENSED/APPROVED FOR MARKETING, IT WILL BE LISTED IN THIS SECTION AND ASTERISKED, AS APPROPRIATE, TO DENOTE MARKETING/EXCLUSIVE APPROVAL STATUS. IN ADDITION, THE EXCLUSIVITY EXPIRATION DATE WILL BE DISPLAYED FOLLOWING THE APPROVED DESIGNATED INDICATION(S).

THE FOLLOWING DRUGS AND BIOLOGICALS HAVE BEEN GRANTED ORPHAN DRUG DESIGNATION PURSUANT TO SECTION 526 OF THE FOOD, DRUG, AND COSMETIC ACT AS AMENDED BY THE ORPHAN DRUG ACT [PUBLIC LAW 97-414].

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: ANTIVENOM (CROTALIDAE) PURIFIED (AVIAN) TRADE: NOT ESTABLISHED	TREATMENT OF ENVENOMATION BY POISONOUS SNAKES BELONGING TO THE CROTALIDAE FAMILY.	OPHIDIAN PHARMA
GENERIC: CYTOMEGALOVIRUS IMMUNE GLOBULIN INTRAVENOUS (HUMAN) TRADE: NOT ESTABLISHED	USE IN CONJUNCTION WITH GANCICLOVIR SODIUM FOR THE TREATMENT OF CYTOMEGALOVIRUS PNEUMONIA IN BONE MARROW TRANSPLANT PATIENTS.	MILES, INC
GENERIC: INTERFERON (RECOMBINANT, BETA) TRADE: R-IFN-BETA	SYSTEMIC TREATMENT OF METASTATIC RENAL CELL CARCINOMA. SYSTEMIC TREATMENT OF CUTANEOUS T-CELL LYMPHOMA. SYSTEMIC TREATMENT OF CUTANEOUS MALIGNANT MELANOMA. INTRALESIONAL AND/OR SYSTEMIC TREATMENT OF AIDS-RELATED KAPOSI'S SARCOMA.	BIOGEN
GENERIC: INTERLEUKIN-3, RECOMBINANT HUMAN TRADE: NOT ESTABLISHED	PROMOTION OF ERYTHROPOIESIS IN DIAMOND-BLACKFAN ANEMIA (CONGENITAL PURE CELL RED APLASIA).	IMMUNEX CORPORATION

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: MUCOID EXOPOLYSACCHARIDE PSEUDOMONAS HYPERIMMUNE GLOBULIN TRADE: MEPIG	TREATMENT OF PULMONARY INFECTIONS DUE TO PSEUDOMONAS AERUGINOSA IN PATIENTS WITH CYSTIC FIBROSIS.	UNIVAX BIOLOGICS, INC
GENERIC: POLY I: POLY $C_{12}U$ TRADE: AMPLIGEN	TREATMENT OF RENAL CELL CARCINOMA.	HEM RESEARCH, INC
GENERIC: RECOMBINANT HUMAN DEOXYRIBONUCLEASE (RHDNASE) TRADE: NOT ESTABLISHED	TO REDUCE MUCOUS VISCOSITY AND ENABLE CLEARANCE OF AIRWAY SECRETIONS IN PATIENTS WITH CYSTIC FIBROSIS.	GENENTECH, INC
GENERIC: RECOMBINANT SECRETORY LEUCOCYTE PROTEASE INHIBITOR TRADE: NOT ESTABLISHED	TREATMENT OF CONGENITAL ALPHA-1 ANTITRYPSIN DEFICIENCY. TREATMENT OF CYSTIC FIBROSIS.	SYNERGEN, INC
GENERIC: RICIN (BLOCKED) CONJUGATED MURINE MONOCLONAL ANTIBODY (ANTI-B4) TO B CELL (CD 19) TRADE: NOT ESTABLISHED	FOR THE EX-VIVO PURGING OF LEUKEMIC CELLS FROM THE BONE MARROW OF NON-T CELL ACUTE LYMPHOCYTIC LEUKEMIA PATIENTS WHO ARE IN COMPLETE REMISSION.	IMMUNOGEN, INC
GENERIC: RICIN (BLOCKED) CONJUGATED MURINE MONOCLONAL ANTIBODY (N901) TO CD56 POSITIVE CELLS TRADE: NOT ESTABLISHED	TREATMENT OF SMALL CELL LUNG CANCER.	IMMUNOGEN, INC
GENERIC: SARGRAMOSTIM TRADE: LEUKINE*/**	TREATMENT OF NEUTROPENIA ASSOICATED WITH BONE MARROW TRANSPLANTS IN PATIENTS WITH NON-HODGKIN'S LYMPHOMA, HODGKIN'S DISEASE AND ACUTE LYMPHOBLASTIC LEUKEMIA. [MAR 5, 1998]	IMMUNEX
GENERIC: THYMOSIN ALPHA-1 TRADE: NOT ESTABLISHED	ADJUNCTIVE TREATMENT OF CHRONIC ACTIVE HEPATITIS B.	ALPHA 1 BIOMEDICALS, INC

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: ALGLUCERASE TRADE: CEREDASE*/**	REPLACEMENT THERAPY IN PATIENTS WITH GAUCHER'S DISEASE TYPE I. [APR 5, 1998]	GENZYME
GENERIC: CALCIUM GLUCONATE GEL TRADE: H-F GEL	EMERGENCY TOPICAL TREATMENT OF HYDROGEN FLUORIDE (HYDROFLUORIC ACID) BURNS.	LTR PHARMACEUTICALS, INC
GENERIC: CYSTEAMINE HCL TRADE: NOT ESTABLISHED	TREATMENT OF NEPHROPATHIC CYSTINOSIS.	WARNER-LAMBERT COMPANY
GENERIC: DEFEROXAMINE AND DEXTRAN TRADE: BIO-RESCUE	TREATMENT OF ACUTE IRON POISONING.	BIOMEDICAL FRONTIERS, INC
GENERIC: DESMOPRESSIN ACETATE TRADE: DDAVP HIGH CONCENTRATION	TREATMENT OF MILD HEMOPHILIA A AND VON WILLEBRAND'S DISEASE.	RORER PHARMACEUTICAL CORP
GENERIC: DRONABINOL TRADE: MARINOL	STIMULATION OF APPETITE AND PREVENTION OF WEIGHT LOSS IN PATIENTS WITH A CONFIRMED DIAGNOSIS OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS).	UNIMED, INC
GENERIC: ETIDRONATE DISODIUM TRADE: DIDRONEL	PREVENTION OF DEGENERATIVE METABOLIC BONE DISEASE OCCURRING IN PATIENTS WHO REQUIRE LONG TERM (6 MONTHS OR GREATER) TOTAL PARENTERAL NUTRITION. TREATMENT OF DEGENERATIVE METABOLIC BONE DISEASE OCCURRING IN PATIENTS WHO REQUIRE LONG TERM (6 MONTHS OR GREATER) TOTAL PARENTERAL NUTRITION.	MGI PHARMA, INC
GENERIC: FLUDARABINE PHOSPHATE TRADE: FLUDARA*/**	TREATMENT OF REFRACTORY B-CELL CHRONIC LYMPHOCYTIC LEUKEMIA. [APR 18, 1998]	BERLEX
GENERIC: GALLIUM NITRATE TRADE: GANITE*/**	TREATMENT OF HYPERCALCEMIA OF MALIGNANCY. [JAN 17, 1998]	FUJISAWA PHARM

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: GENTAMICIN IMPREGNATED PMMA BEADS ON SURGICAL WIRE TRADE: SEPTOPAL	TREATMENT OF CHRONIC OSTEOMYELITIS OF POST-TRAUMATIC, POSTOPERATIVE OR HEMATOGENOUS ORIGIN.	E. MERCK, DARMSTADT
GENERIC: HISTRELIN TRADE: NOT ESTABLISHED	TREATMENT OF ACUTE INTERMITTENT PORPHYRIA, HEREDITARY COPROPORPHYRIA, AND VARIEGATE PORPHYRIA.	KARL E. ANDERSON, M.D. UNIVERSITY OF TEXAS
GENERIC: IDARUBICIN HCL TRADE: IDAMYCIN	TREATMENT OF ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) IN PEDIATRIC PATIENTS.	ADRIA
GENERIC: KETOCONAZOLE TRADE: NOT ESTABLISHED	FOR USE WITH CYCLOPORIN A TO DIMINISH THE NEPHROTOXICITY INDUCED BY CYCLOSPORIN IN ORGAN TRANSPLANTATION.	PHARMEDIC COMPANY
GENERIC: OFLOXACIN TRADE: NOT ESTABLISHED	TREATMENT OF BACTERIAL CORNEAL ULCERS.	ALLERGAN, INC
GENERIC: PENTOSTATIN TRADE: NOT ESTABLISHED	TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA.	WARNER LAMBERT COMPANY
GENERIC: POLOXAMER 331 TRADE: PROTOX	INITIAL THERAPY OF TOXOPLASMOSIS IN PATIENTS WITH ACQUIRED IMMUNODEFICIENCY SYDROME (AIDS).	CYTRX CORPORATION
GENERIC: RECOMBINANT HUMAN SUPEROXIDE DISMUTASE TRADE: NOT ESTABLISHED	PREVENTION OF BRONCHOPULMONARY DYSPLASIA IN PREMATURE NEONATES WEIGHING LESS THAN 1500 GMS.	BIO TECHNOLOGY GENERAL CORP
GENERIC: RIBAVIRIN TRADE: VIRAZOLE	TREATMENT OF HEMORRHAGIC FEVER WITH RENAL SYNDROME.	ICN PHARMACEUTICALS, INC
GENERIC: SUCCIMER TRADE: CHEMET*/**	TREATMENT OF LEAD POISONING IN CHILDREN.*/** [JAN 30, 1998] TREATMENT OF MERCURY INTOXICATION.	MCNEIL
GENERIC: SUCRALFATE TRADE: NOT ESTABLISHED	TREATMENT OF ORAL ULCERATIONS AND DYSPHAGIA IN PATIENTS WITH EPIDERMOLYSIS BULLOSA.	NASKA PHARMCAL CO

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: TESTOSTERONE SUBLINGUAL TRADE: NOT ESTABLISHED	TREATMENT OF CONSTITUTIONAL DELAY OF GROWTH AND PUBERTY IN BOYS.	GYNEX, INC
GENERIC: URSODEOXYCHOLIC ACID TRADE: ACTIGALL	MANAGEMENT OF THE CLINICAL SIGNS AND SYMPTOMS ASSOCIATED WITH PRIMARY BILIARY CIRRHOSIS.	CIBA GEIGY

DRUG PRODUCTS WHICH MUST DEMONSTRATE IN VIVO BIOAVAILABILITY ONLY IF PRODUCT FAILS TO ACHIEVE ADEQUATE DISSOLUTION

NO MAY 1991 ADDITIONS

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

THE FOLLOWING IS A LIST OF GUIDANCES AVAILABLE FOR IN VIVO BIOEQUIVALENCE STUDIES AND IN VITRO DISSOLUTION TESTING AVAILABLE FROM THE DIVISION OF BIOEQUIVALENCE, HFD-650, MPN-2 ROOM 278, 5600 FISHERS LANE, ROCKVILLE, MD 20857. COMMENTS AND SUGGESTIONS CONCERNING THESE GUIDANCES ARE ENCOURAGED AND SHOULD BE SENT TO THE DIVISION OF BIOEQUIVALENCE.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 11TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

NO MAY 1991 ADDITIONS

ANDA SUITABILITY PETITIONS

THE FOLLOWING ARE TWO LISTS OF PETITIONS FILED UNDER SECTION 505(j)(2)(C) OF THE ACT WHERE THE AGENCY HAS DETERMINED THAT THE REFERENCED PRODUCT: (1) IS SUITABLE FOR SUBMISSION AS AN ANDA (PETITIONS APPROVED) OR (2) IS NOT SUITABLE FOR SUBMISSION AS AN ANDA (PETITIONS DENIED). THE DETERMINATION THAT AN ANDA WILL BE APPROVED IS NOT MADE UNTIL THE ANDA ITSELF IS SUBMITTED AND REVIEWED BY THE AGENCY. A COPY OF EACH PETITION IS LISTED BY DOCKET NUMBER ON PUBLIC DISPLAY IN FDA'S DOCKETS MANAGEMENT BRANCH, HFA-305, ROOM 4-62, 5600 FISHERS LANE, ROCKVILLE, MD 20857.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 11TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
CARBAMAZEPINE SUSPENSION; ORAL	200MG/5ML	89 P-0399/CP	GUIDELINES	NEW DOSAGE FORM	APPROVED MAY 16, 1991
CLOBETASOL PROPIONATE LOTION; TOPICAL	0.05%	90 P-0198/ CP1	KROSS	NEW DOSAGE FORM	APPROVED MAR 14, 1991
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	100MG/VIAL	90 P-0250/ CP1	PHARMACHEMIE	NEW DOSAGE FORM	APPROVED MAY 07, 1991
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	200MG/VIAL	90 P-0250/ CP2	PHARMACHEMIE	NEW DOSAGE FORM	APPROVED MAY 07, 1991
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	500MG/VIAL	90 P-0250/ CP3	PHARMACHEMIE	NEW DOSAGE FORM	APPROVED MAY 07, 1991
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	1GM/VIAL	90 P-0250/ CP4	PHARMACHEMIE	NEW DOSAGE FORM	APPROVED MAY 07, 1991
DOPAMINE HYDROCHLORIDE INJECTABLE; INJECTION	5MG/ML	90 P-0137/ CP1	ABBOTT	NEW STRENGTH	APPROVED APR 10, 1991

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
ETOPOSIDE INJECTABLE; INJECTION	20MG/ML (25ML/VIAL)	91 P-0041/ CP1	ADRIA	NEW STRENGTH	APPROVED MAY 22, 1991
ESTRADIOL FILM, EXTENDED RELEASE; TRANSDERMAL	0.067MG/24HR	90 P-0125/ CP1	NOVEN PHARMS	NEW STRENGTH	APPROVED MAR 14, 1991
ESTRADIOL FILM, EXTENDED RELEASE; TRANSDERMAL	0.084MG/24HR	90 P-0125/ CP2	NOVEN PHARMS	NEW STRENGTH	APPROVED MAR 14, 1991

EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMN, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 11TH EDITION FOR A FULL LISTING OF EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEUDLE, NEW INDICATIONS AND PATENT USE CODES). ONLY NEW CODES WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

REFERENCES
NEW INDICATION

I-55	HYPERTENSION
I-56	EROSIVE GASTROESOPHAGEAL REFLUX DISEASE

REFERENCES
PATENT USE CODE

U-44	RELIEF OF NAUSEA AND VOMITING
U-45	TREATMENT OF INFLAMMATION AND ANALGESIA
U-46	TREATMENT OF PANIC DISORDER
U-47	STIMULATION OF THE RELEASE OF GROWTH HORMONE
U-48	ANALGESIA

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	20089 001	ACYCLOVIR; ZOVIRAX	4199574	APR 22, 1997			
>ADD>	20089 002	ACYCLOVIR; ZOVIRAX	4199574	APR 22, 1997			
						NCE	APR 05, 1996
	20057 003	ALGLUCERASE; CEREDASE				ODE	APR 05, 1998
	18276 001	ALPRAZOLAM; XANAX	4508726	APR 02, 2002	U-46		
	18276 002	ALPRAZOLAM; XANAX	4508726	APR 02, 2002	U-46		
	18276 003	ALPRAZOLAM; XANAX	4508726	APR 02, 2002	U-46		
	18276 004	ALPRAZOLAM; XANAX	4508726	APR 02, 2002	U-46		
	19926 001	ALTRETAMINE; HEXALEN	3980789	SEP 14, 1993			
	18700 001	AMRINONE LACTATE; INOCOR				ODE	DEC 26, 1997
>ADD>	19856 001	CARBIDOPA; SINEMET CR	4072746	APR 23, 1998	U-7	NCE	JUL 31, 1994
>ADD>			4900755	MAY 23, 2006			
>ADD>			4832957	MAY 23, 2006			
	17920 002	CIMETIDINE; TAGAMET	3830827	AUG 20, 1991			
	17920 003	CIMETIDINE; TAGAMET	3950333	APR 13, 1993		I-56	MAR 07, 1994
	17920 004	CIMETIDINE; TAGAMET	3950333	APR 13, 1993		I-56	MAR 07, 1994
	17920 005	CIMETIDINE; TAGAMET	3950333	APR 13, 1993		I-56	MAR 07, 1994
	17924 001	CIMETIDINE HYDROCHLORIDE; TAGAMET	3950333	APR 13, 1993		I-56	MAR 07, 1994
	19849 001	DAPIPRAZOLE HYDROCHLORIDE; REV-EYES	3950333	APR 13, 1993		I-56	MAR 07, 1994
	19082 001	DEZOCINE; DALGAN	4252721	FEB 24, 1998		NCE	DEC 31, 1995
			4001331	JAN 04, 1996		NCE	DEC 29, 1994
	19082 002	DEZOCINE; DALGAN	3836670	SEP 09, 1991	U-48		
			4001331	JAN 04, 1996		NCE	DEC 29, 1994
	19082 003	DEZOCINE; DALGAN	3836670	SEP 09, 1991	U-48		
			4001331	JAN 04, 1996		NCE	DEC 29, 1994
	20037 001	DICLOFENAC SODIUM; VOLTAREN	3836670	SEP 09, 1991	U-48		
	18723 001	DIVALPROEX SODIUM; DEPAKOTE	3652762	MAR 28, 1991		NDF	MAR 28, 1994
	18723 002	DIVALPROEX SODIUM; DEPAKOTE	4988731	JAN 29, 2008			
	18723 003	DIVALPROEX SODIUM; DEPAKOTE	4988731	JAN 29, 2008			
	19680 001	DIVALPROEX SODIUM; DEPAKOTE	4988731	JAN 29, 2008			
	19794 001	DIVALPROEX SODIUM; DEPAKOTE CP	4988731	JAN 29, 2008			
	19794 002	DIVALPROEX SODIUM; DEPAKOTE CP	4988731	JAN 29, 2008			
	19946 001	DOXACURIUM CHLORIDE; NUROMAX	4701460	OCT 20, 2004		NCE	MAR 07, 1996
	19668 001	DOXAZOSIN MESYLATE; CARDURA	4188390	FEB 12, 1997		NCE	NOV 02, 1995
	19668 002	DOXAZOSIN MESYLATE; CARDURA	4188390	FEB 12, 1997		NCE	NOV 02, 1995
	19668 003	DOXAZOSIN MESYLATE; CARDURA	4188390	FEB 12, 1997		NCE	NOV 02, 1995
	19668 004	DOXAZOSIN MESYLATE; CARDURA	4188390	FEB 12, 1997		NCE	NOV 02, 1995

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	19653 001	ETHINYL ESTRADIOL; ORTHO CYCLEN-21	4027019	MAY 31, 1998		NC	DEC 29, 1992
	19653 002	ETHINYL ESTRADIOL; ORTHO CYCLEN-28	4027019	MAY 31, 1998		NC	DEC 29, 1992
	18922 002	ETODOLAC; LODINE	4076831	FEB 28, 1995	U-45		
			3939178	FEB 17, 1993		NCE	JAN 31, 1996
	18922 003	ETODOLAC; LODINE	4076831	FEB 28, 1995	U-45		
			3939178	FEB 17, 1993		NCE	JAN 31, 1996
	19949 001	FLUCONAZOLE; DIFLUCAN	4404216	OCT 16, 2003		NCE	JAN 29, 1995
	19949 002	FLUCONAZOLE; DIFLUCAN	4404216	OCT 16, 2003		NCE	JAN 29, 1995
	19949 003	FLUCONAZOLE; DIFLUCAN	4404216	OCT 16, 2003		NCE	JAN 29, 1995
	19950 001	FLUCONAZOLE; DIFLUCAN	4404216	OCT 16, 2003		NCE	JAN 29, 1995
	20038 001	FLUDARABINE PHOSPHATE; FLUDARA	4357324	NOV 02, 1999		NCE	APR 18, 1996
						ODE	APR 18, 1998
	20101 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4314081	FEB 02, 2001		NCE	DEC 29, 1992
>ADD>	19915 002	FOSINOPRIL SODIUM; MONOPRIL	4384123	MAY 17, 2000			
>ADD>			4337201	JUN 29, 1999		NCE	MAY 16, 1996
>ADD>	19915 003	FOSINOPRIL SODIUM; MONOPRIL	4384123	MAY 17, 2000			
>ADD>			4337201	JUN 29, 1999		NCE	MAY 16, 1996
	19961 002	GALLIUM NITRATE; GANITE				NCE	JAN 17, 1996
						ODE	JAN 17, 1998
	19967 001	HALOBETASOL PROPIONATE; ULTRAVATE	4619921	OCT 28, 2003		NCE	DEC 17, 1995
	19968 001	HALOBETASOL PROPIONATE; ULTRAVATE	4619921	OCT 28, 2003		NCE	DEC 17, 1995
	19546 001	ISRADIPINE; DYNACIRC	4466972	AUG 21, 2001	U-3	NCE	DEC 20, 1995
	19546 002	ISRADIPINE; DYNACIRC	4466972	AUG 21, 2001	U-3	NCE	DEC 20, 1995
	18686 001	LABETALOL HYDROCHLORIDE; NORMODYNE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
	18687 001	LABETALOL HYDROCHLORIDE; NORMODYNE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
	18687 002	LABETALOL HYDROCHLORIDE; NORMODYNE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
	18687 003	LABETALOL HYDROCHLORIDE; NORMODYNE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
	18687 004	LABETALOL HYDROCHLORIDE; NORMODYNE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
	18716 001	LABETALOL HYDROCHLORIDE; TRANDATE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
	18716 002	LABETALOL HYDROCHLORIDE; TRANDATE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
	18716 003	LABETALOL HYDROCHLORIDE; TRANDATE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
	18716 004	LABETALOL HYDROCHLORIDE; TRANDATE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
	19425 001	LABETALOL HYDROCHLORIDE; TRANDATE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
>ADD>	20035 001	LEVAMISOLE HYDROCHLORIDE; ERGAMISOL	4584305	JUN 19, 2004	U-42	NCE	JUN 18, 1995
>DLT>	20035 001	LEVAMISOLE HYDROCHLORIDE; ERGAMISOL	4584305	APR 22, 2003	U-42	NCE	JUN 18, 1995
	20088 001	LEVONORGESTREL; NORPLANT SYSTEM	3850911	NOV 26, 1991		NP	DEC 10, 1993

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19753 001	MORICIZINE HYDROCHLORIDE; ETHMOZINE	3864487	FEB 04, 1994		NCE	JUN 19, 1995
19753 002	MORICIZINE HYDROCHLORIDE; ETHMOZINE	3864487	FEB 04, 1994		NCE	JUN 19, 1995
19753 003	MORICIZINE HYDROCHLORIDE; ETHMOZINE	3864487	FEB 04, 1994		NCE	JUN 19, 1995
19886 001	NAFARELIN ACETATE; SYNAREL	4234571	NOV 18, 2001		NCE	FEB 13, 1995
19684 001	NIFEDIPINE; PROCARDIA XL	4783337	SEP 16, 2003		I-55	SEP 06, 1992
		4765989	SEP 16, 2003		D-2	SEP 06, 1992
19684 002	NIFEDIPINE; PROCARDIA XL	4783337	SEP 16, 2003		I-55	SEP 06, 1992
		4765989	SEP 16, 2003		D-2	SEP 06, 1992
19684 003	NIFEDIPINE; PROCARDIA XL	4783337	SEP 16, 2003		I-55	SEP 06, 1992
		4765989	SEP 16, 2003		D-2	SEP 06, 1992
20007 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4753789	JUN 28, 2005	U-44	NCE	JAN 04, 1996
		4695578	SEP 22, 2004			
18631 001	PENTOXIFYLLINE; TRENTAL	3737433	APR 03, 1997		NCE	AUG 30, 1994
19456 001	PINACIDIL; PINDAC	RE31244	NOV 08, 1996	U-3	NCE	DEC 28, 1994
19456 002	PINACIDIL; PINDAC	RE31244	NOV 08, 1996	U-3	NCE	DEC 28, 1994
19797 001	POLYETHYLENE GLYCOL 3350; NULYTELY				NP	APR 22, 1994
19901 001	RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
19901 002	RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
19901 003	RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
19901 004	RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
19863 001	SERMORELIN ACETATE; GEREF	4703035	MAY 14, 2002	U-47	NCE	DEC 28, 1995
		4517181	MAY 14, 2002		NCE	DEC 28, 1995
19998 002	SUCCIMER; CHEMET				NCE	JAN 30, 1996
					ODE	JAN 30, 1998
19785 001	TECHNETIUM TC-99M SESTAMIBI KIT; CARDIOLITE	4452774	JUN 05, 2001		NCE	DEC 21, 1995
19785 002	TECHNETIUM TC-99M SESTAMIBI KIT; CARDIOLITE	4452774	JUN 05, 2001		NCE	DEC 21, 1995